

October 21, 2003

Dr. Stephen Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration 7500 Standish Place Rockville, MD 20855

Fax: 301-827-4401

Re: Compliance Policy Guide on Compounding for Animals.

Dear Dr. Sundlof:

Please consider withdrawing this un-challenged policy and rewriting it with input from those involved, such as veterinarians, compounding pharmacists, and pet owners. Compounding for humans from bulk active pharmaceuticals has been an accepted practice for years, and to disallow this for non-food animals is very problematic and will warrant much investigation on underlying reasoning.

We are involved with many top notch veterinarians across the country, have a vet consultant on staff, and we are highly respected in our knowledge of vet medicine. This ruling certainly is very disconcerting for not only us, but our clients.

I am anxious to hear your feedback on this issue which, to this point, has had no public discussion.

Sincerely,

Bob Bishop, RPh

Compounding Specialist, ApothéCure, Inc.

bbishop@apothecure.com

cc: Mark McClelland, FDA Commissioner

US Senator Kay Bailey Hutchison (R-TX)

US Senator John Cornyn (R-TX)

US Representative Pete Sessions (R-TX 32nd)

State Senator Florence Shapiro (R-8)

State Representative Ken Marchant (R-115)

L.D. King. IACP Executive Director



October 21, 2003

Dr. Stephen Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration 7500 Standish Place Rockville, MD 20855

Fax: 301-827-4401

Re: Compliance Policy Guide on Compounding for Animals

Dear Dr. Sundlof:

Please consider withdrawing this un-challenged policy and rewriting it with input from those involved, such as veterinarians, compounding pharmacists, and pet owners. Compounding for humans from bulk active pharmaceuticals has been an accepted practice for years, and to disallow this for non-food animals is very problematic and will warrant much investigation on underlying reasoning.

We are involved with many top notch veterinarians across the country, have a vet consultant on staff, and we are highly respected in our knowledge of vet medicine. This ruling certainly is very disconcerting for not only us, but our clients.

I am anxious to hear your feedback on this issue which, to this point, has had no public discussion.

Sincerely,

Sheri Bedell, RPh

Staff Pharmacist, ApothéCure, Inc.

Sheri Bedell

sbedell@apothecure.com

cc: Mark McClelland, FDA Commissioner

US Senator Kay Bailey Hutchison (R-TX)

US Senator John Cornyn (R-TX)

US Representative Pete Sessions (R-TX 32nd)

State Senator Florence Shapiro (R-8)

State Representative Ken Marchant (R-115)

L.D. King, IACP Executive Director

P.O. BOX 664 CAMERON, SC 29030 803-823-2104

OCTOBER 23, 2003

DR. STEPHEN SUNDLOF, DIRECTOR CENTER FOR VETERINARY MEDICINE U.S. FOOD AND DRUG ADMINISTRATION

MARK SMITH, RPH CAMERON PHARMACY PO BOX 664 CAMERON, SC 29030

DEAR SIR:

I AM A COMPOUNDING PHARMACIST IN THE VETERINARY COMPOUNDING BUSINESS. WE COMPOUND FOR NON-FOOD GRADE ANIMALS ONLY. YOUR AGENCY HAS SEVERAL ISSUES AT HAND THAT ARE VERY DETRIMENTAL TO MY COMPOUNDING BUSINESS.

- 1. THE CVM ISSUED THE COMPLIANCE POLICY GUIDE (CPG) IN FINAL FORM WITHOUT ALLOWING OPPORTUNITY FOR COMMENTS. THIS IS IN VIOLATION OF THE FDA GOOD GUIDANCE PRACTICES. MANY REQUIREMENTS OF THIS CPG ARE EXTREMELY PROBLEMATIC AND DESERVE A COMMENT PERIOD.
- 2. FDA'S PROHIBITION IN THE CPG AGAINST COMPOUNDING FROM BULK ACTIVE PHARMACEUTICALS IS EXTREMELY PROBLEMATIC. IT IS ESSENTIAL THAT PHARMACISTS BE ALLOWED TO COMPOUND FOR NON-FOOD PRODUCING ANIMALS FROM BULK CHEMICALS.

I AM REQUESTING THAT THE FDA WITHDRAW THE CPG AND REISSUE IT IN DRAFT FORM TO ALLOW PHARMACISTS, VETERINARIANS, AND PATIENTS THE OPPORTUNITY TO COMMENT ON ITS PROVISIONS BEFORE IT IS IMPLEMENTED.

SINCERELY

MARK T. SMITH, RPH.

Ce: MARK MCCLELLAN. FDA COMMISSIONER

> SEN. ERNEST F. HOLLINGS SEN. LINDSAY GRAHAM REP. JOE WILSON REP. JAMES CLYBURN JACP



October 2, 2003

Dr. Stephen Sundlof, Director Center for Veterinary Medicine. U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855

Dear Dr. Sundlof:

As you know, your agency recently issued a Compliance Policy Guide on compounding for animals that disallows all compounding from bulk pharmaceutical ingredients.

Unfortunately, it also includes all non-food animals. I don't have to remind you that this policy is more restrictive than your own agency's policies governing compounding for human patients. Further, it was issued in final form, without any opportunity for comments.

As compounding pharmacists, we are asking you to rescind this and reissue it in draft form, as this would allow adequate time for comments from compounding pharmacists, veterinarians, and patients.

Sincerely,

Gary Osborn, RPh.

obe Ganucci, RPA

Bob Bishop, RPh

cc:

Dr. Mark McClellan, FDA Commissioner

Senator Kay Bailey Hutchinson

Senator John Cornyn

Representative Pete Sessions

L. D. King, Executive Director IACP



October 2, 2003:

BRISTOL, CT 06010

25 Collins Road 860 589 5587

57 South Street 860 583 1006

EAST HAVEN, CT 06513

875 Foxon Road 203 467 1642

NEW BRITAIN, CT 06053

543 West Main Street 860 225 6487

ROCKYILLE, CT 06066

40 West Main Street 860 875 9263

SOUTHINGTON, CT 08469

340 North Main Street 860 628 3972

TERRYVILLE, CT 06786

241 Main Street 860 585 5158

WATERBURY, CT 08705

2152 East Main Street 203 755 7222

WILLIMANTIC, CT 06226

972 Main Street 860 423 1410

WINSTED, CT 06098

294 Main Street 860 738 2506

www.BeaconRx.com

To Whom it May Concern:

Having just spent a significant sum of money on training to. become a compounding phar nacist, the new Compliance Policy Guide (CPG) issued by the FDA Center of Veterinary Medicine (CVM) is a devastating blow.

CVM issued this CPG in final form without allowing opportunity for comments, in violation of IDA Good Guidance Practices: Many requirements of this CFG are extremely problematic and deserve a comment period before being put into effect.

FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essentialthat pharmacists be allowed to compound for non-food producing animals from bulk thrug substances.

Please withdraw the CPG and reissue it as a draft to allow for comments on its provisions before it is implemented.

Regards,

Elliott Colasanto, RPn.

Beacon Prescriptions Southington

340 North Main Street

Southington, CT 06489 Phone: (860) 628-3972

Fax: (860) 621-3972.

Email: e.colasanto@sbcglob#I.net

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- imber 29, 2003

A seconen Sundlof, Director

Action for Veterinary Medicine

Second and Drug Administration (HFV-1)

The Standish Place

Second MD 20855



Compliance Policy Guide for Veterinary Medicine (CPGVM)

was rector Sundlof.

You are lucky you work in Maryland and you are not an elected official.

Authornia, we recall elected officials who do not understand the principles a guide our government "of and by the people".

You are allowing the FDA to ignore its own policy by creating the the vacuum of a bureaucracy and by allowing the viewpoint of a way appear of nameless individuals to dictate a regulatory policy that:

- Has no basis in law.
- Jindermines the authority of licensed veterinarians:

assumes pet owners do not have the ability to make rational decisions. Feduces drug research in non-food producing animals (CPGVM does not allow for INDs from bulk active pharmaceuticals).

Eliminates the traditional pharmacist role in providing cost-effective workable cures to veterinarians who are responsible for the treatment of the unique ailments of non-food producing animals.

2 acrasticas ?

- How many of the people who created the CPGVM truly understand the veterinarian compounding needs in the daily operation of a zoo?
- * # many of the people who created the CPGVM understand the compounding needs of veterinarians dealing with the unique infections at racehorses in South Florida during the rainy season?
- who many of the people who created the CPGVM understand the veterinarian compounding needs of a Seal Rescue Center in Southern California?
- could go on and on and on.

How have chosen to ignore the requirement for public comments in a section of the FDA's own Good Guidance Practices. The FDA as a whole section very hard with the industry it regulates to provide accurate, impartial enformation and regulations. Your actions and the actions of your staff-through the integrity of the FDA and all hard working FDA employees.

McGUEE

MEDICAL

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EMAIL: answers@rneguif com

I request that you WITHDRAW the current biased and ill thought CPGVM prior to its implementation and replace it with a Compliance Policy that is formulated with the best interests of the people and the government.

By utilizing the FDA Good Guidance Practices, (with public comment). you have the ability to create industry standards that make sense to both the regulators and the regulated. You have the moment in hand to make a great contribution to veterinary medicine, pharmacy and thousands of pet owners... lets do it right.

Sincerely and Respectfully McGuff Company, Inc.

Ronald M. McGuff President/CEO

cc: Mark McClellan, FDA Commissioner

cc: Senator Dianne Feinstein cc: Senator Barbara Boxer

cc: Congressman Dana Rohrabacher.

cc: International Association of Compounding Pharmacists

cc: Mark McClellan, FDA Commissioner cc: Senator Ben-Nighthorse-Campbell cc: Senator Wayne Allard cc: Representative Bob-Beauprez cc: IACP

Dr. Stephen Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855

Dear Dr. Sundlof:

My name is Kelby D. Gorman and I am a compounding pharmacist in Sinton, TX:

1 am writing to you because of concerns I have with the new Compliance Policy Guide
(CPG) recently issued. CVM issued this Compliance Policy Guide in final form without
allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many
requirements of this CPG are extremely problematic and deserve a comment period
before being put into effect. FDA's prohibition in this CPG against compounding from
bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be
allowed to compound for <u>won-food</u> producing animals from bulk drug substances.

I am writing to ask the FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented. Please take these concerns of mine into consideration.

Kelby D. Gorman, R.Ph.

101 W. Sinton Street

Sinton, TX 78387

800-734-2418

361-364-5028 (fax)

www.moorespharmacy.com

Vice-President

MOORES PHARMACY

KDG:lmm

cc: Mark McClellan, FDA Commissioner

Sen. Kay Bailey Hutchinson

Sen. John Cornyn

Rep. Ruben Hinojosa

IACP



September-29, 2003

Dr. Stephen Sundlof, Director Center for Veterinary Medicine. U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855

Dear Dr. Sundlof:

I recently became aware of the U.S. Food and Drug Administration (FDA) Center for Veterinary Medicine's (CVM) rash introduction of a Compliance Policy Guide (CPG) on compounding for animals. I understand that this policy disallows all compounding from bulk pharmaceutical ingredients. This is a standard that is much more restrictive than FDA's policies governing compounding for human patients:

I am concerned about this policy for many reasons the first being that CVM issued this CPG in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect. FDA's prohibition in this CPG against compounding from bulk active pharmacists is again extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

I am asking that the FDA withdraw the CPG and reissue it in draft form to allow pharmacists, veterinarians, and patients to comment on it's provisions before it is implemented.

Sincerely,

Gary Heffner
Owner/Rph

Family Pharmacy (253)839-3100

Hofner Reh

cc: Mark Mclellan, FDA Comm., cc: Sen. Maria Cantwell, cc: Sen. Patti Murray,

cc:Rep. Adam Smith, cc: IACP

ab

Professional Arts Apothecary 1401 Harrodsburg Rd., B155 Lexington, KY 40504

Charles W. Peal, R.Ph.
Phone 859-276-3905 Fax 859-277-0252

Sept. 29, 2003

Dr. Stephen Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug 7500 Standish Place Rockville; MD-20\$55

Dear Sir.

I have noted that CVM has issued a CPG, that will not allow Pharmaeist in the U. S. to compound prescriptions for animals. This is probably a good idea for food animals, but is a bad idea for family pets. I have a number of customers, who have cats as family pets. As you probably know cats are very hard to dose orally. I have to make their thyroid medicine into a gel formula to be rubbed into their ears. If I am not allowed to continue compounding these prescriptions these cats may die, because the owner can not get the thyroid medicine down them orally.

Please withdraw the CPA and reissue it in draft form to allow pharmacist, veterinarians, and patients time to address this issue.

Thank you.

yours truly,

Charles W. Peal, R.Ph.

cc: Mark McCelellan, FDA Commissioner

cc: Senator Mitch McConnell

cc: Senator Jim Bunning

cc: Representative Ernie Fletcher-

cc. IACP

2450-169th Street Hammond, IN 46323 Tel: 219.845.2900 Fax: 219.844.1983

E-mail: info@vytospharmacy.com

VYTO'S PHARMACY

September 30, 2003

Dr. Stephen F. Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, Maryland 20855

Dear Dr. Sundlof

Please accept the following reservations I have with your recently-issued guidance:

- A. The Center for Veterinary Medicine (CVM) issued this Compliance Policy Guide (CPG) in final form without allowing opportunity for comments in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect.
- B. FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

The FDA should withdraw the CPG and reissue it in draft form so that pharmacists, veterinarians, and patients are able to comment on its provisions prior to its implementation.

Yours truly.

Vyto J. Damasius, R.Ph.

Cc: Mark McClellan, FDA Commissioner

Co. Sen. Dick Lugar, Sen. Evan Bayh, Rep. Pete Visclosky-

Cc: JACP

Your Community Pharmacy

September 30, 2003.

Dr. Stephen Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855

Dear Dr. Sundlof

This letter is in regards to the issuance of a Compliance Policy Guide that would disallow using bulk pharmaceutical ingredients to compound medications for non-food producing animals. The Compliance Policy Guide was issued in final form and no opportunity was available for comments by pharmacists, veterinarians, or patients of non-food producing animals. Many aspects of this policy guide are very problematic for all parties involved and require some input before it is set in stone.

Please withdraw the Compliance Policy Guide and reissue it in draft form to allow time for comments and possible corrections.

Thank you,

Justin J. Meyers, Pharm D Student

cc: Mark McClellan, FDA Commissioner

cc: Senator Arlen Specter cc: Senator Rick Santorum

cc: Representative Joseph Hoeffel III.

cc: IACP

September 30; 2003 Mulberry Pharmacy Inc PO Box 767 1009 North Church Mulberry FL., 33860

Dr. Stephen Sundlof, Director
US Food and Drug Administration (HFV₇1)
7500 Standish Place
Rockville, MD- 20855

Dear Dr. Sundiof.

This letter is to inform you of my concern with the CVM Compliance Policy Guide (CPG). It was brought to my attention that this was issued in a final form without any opportunities for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into practice.

The FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for nonfood producing animals from bulk drug substances. Since veterinarians in Florida also fall under all provisions of pharmacy law, you are also depriving veterinarians from using bulk chemicals in making dosage forms for their patients.

This practice would disallow compounding pharmacies to make many compounds for our animal patients. Currently, by using bulk agents, we are able to deliver a quality compounded prescription for a much reduced price: Your new policies would increase the price on medicines to animals by forcing both the compounding pharmacy and veterinarian to buy in small units, or by reducing competition by allowing only commercial manufacturers the ability to make medications for nonfood producing animals (and the track record for such medications are abysmal- the manufacturers routinely drop the production of veterinarian products.)

By enacting this CPG you are essentially depriving the compounding pharmacy from a integral part of it's practice and denying and restricting a patient and owner the ability to freely choose to get their prescription filled at a local compounding pharmacy, as well as increasing final price of any new medication. You are also restricting a veterinarian from choosing unique medications and delivery systems for his animal patients.

I ask that the FDA withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians and patients to comment on it's provisions before it is implemented.

Sincerely yours,

Thomas Slaughter, PharmD

Mulberry Pharmacy

Contact. (863) 425-1101 Voice • (863) 425-2802 (Fax)

cc: Mark McClellan, FDA Commissioner

cc. Senator Bob Graham, Senator Bill Nelson, Representative Adam Putnam

cc. IACP

Mulberry Pharmacy has been serving the people of Mulberry Florida and it's surrounding communities since the early 1900's. It has been owned and operated since 1957 by Jerold Slaughter, RPh, graduate of the University of Florida. Between Mr. Slaughter and Mr. Pettijohn (Southern School of Pharmacy, 1959), the pharmacists at Mulberry Pharmacy have over 70 years of pharmacy experience.

George W Warren Jr., RPh 2805 Joanna Drive Eustis, Fl 32726 352-589-1812

September 29, 2003

Dr. Stephen Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855

Dear Dr. Sundlof,

I am writing you today in regards to the recently issued Compliance Policy Guide (CPG) that prohibits compounding from bulk active pharmaceuticals and our ability, as pharmacists, to participate with veterinarians in the care of our non-food producing friends.

I understand from my connection with the International Association of Compounding Pharmacists (IACP) that this CPG was issued without the comment period described in the FDA Good Guidance Practices.

In my practice as a compounding pharmacist, I work with local vets to solve real problems from hyperthyroidism in cats to epilepsy in dogs. Final desage forms are important for compliance and bioavailability. To prohibit the use of bulk substances from compounding by pharmacists is a step backwards in the care provided to non-food producing animals.

I am asking for the FDA to withdraw the final CPG and reissue it in draft form for comment by pharmacists, veterinarians and pet owners before final implementation. I would happily volunteer to help in the comment period to further describe what I do as a compounding pharmacist.

Thank you for your time.

George W Warren Jr., RPh Owner, Lake Pharmacy

cc: Mark McClellan, FDA Commissioner

cc: Sen. Bob Graham cc: Sen. Bill Nelson cc: Rep. Ric Keller

cc: International Association of Compounding Pharmacists (IACP)

Lake Pharmacy
"Medication Problem Solvers"

George W Warren; Jr., RPh
PresidentiCEO
710 North Bay Street
Eustrs, Florida 32726

Phone: 352-357-5485
Fax; 352-357-5505
E-mail: flarph@aol.com

September 30, 2003

Dr. Stephen Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof,

I am writing because I am concerned about the FDA's veterinary compounding Compliance Policy Guide (CPG) and the effects this will have on the ability to provide proper medicinal treatment for animals. The FDA issued this CPG in final form without allowing the opportunity for comments from the people who know most about the issue (compounding pharmacists, veterinarians, and pet owners). This was done in violation of FDA Good Guidance Practices which allow for the comment period.

The FDA has said that medications cannot be made from bulk ingredients for animals. This makes no sense whatsoever. As a pharmacist, I make medications every day for people out of bulk ingredients. I see no reason why I should not be allowed to do the same for non-food producing animals. Furthermore, it is essential that I be allowed to do this because in many instances, it is the only treatment option available for pets.

The FDA should, according to it's own Good Guidance Practices, withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and petowners/advocates to comment on its provisions before it is implemented.

Thank You,

Amy Kille, Pharm.D.

Our Will

Pharmacy Manager

North Oak Pharmacy and Wellness Center

4260 N. Oak Trafficway

Kansas City, MO 64116

816-453-1050

Fax: 816-453-3102

cc: Mark McClellan, FDA Commissioner

Senators Kit Bond and Jim Talent Representative Karen McCarthy

Institute for the Advancement of Community Pharmacy (IACP)

402 311 3000



Vital Care Pharmacy of Norfolk

Home Infusion Services Prescription Compounding 1310 N. 13th St., Suite 3 Norfolk, NE 68701 Phone: (402) 371-3444 Fax: (402) 371-3566

e-mail: vitalcare@conpoint.com



September 30, 2003.

Dr. Stephen Sundlof, Director Center for Veterinary Medicine-U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855

Dear Sir:

We are a local pharmacy providing extemporaneous compounding of medications for the veterinarians in our area when a commercial product is not available for the specific animal's need. I understand that the U.S. Food and Drug Administration Center for Veterinary Medicine (CVM) recently issued a Compliance Policy Guide (CPG) on compounding for animals that disallows all compounding from bulk pharmaceutical ingredients, a standard that is much more restrictive than FDA's policies governing compounding for human patients. CVM issued this CPG in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect.

FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substance. I have compounded medications for cats and dogs to control their symptoms when a commercial product or strength was not available (e.g. potassium bromide for seizures in a dog; cisapride 2.5mg capsules for a cat, etc.)

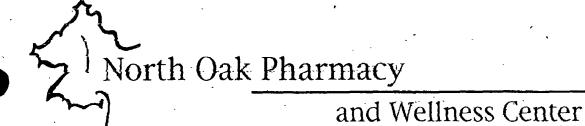
I am asking the FDA to withdraw the CPG and reissue it in draft from to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Sincerely

Kim Kortje, PharmD

Co-owner

Cc: Mark McClellan, FDA Commissioner; IACP: Cc: Senators Hagel & Nelson; Rep. Bereuter



November 13, 2003

Dr. Stephen Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration 7500 Standish Place Rockville, MD 20855

Dear Dr. Sundlof:

I am writing due to my concern with the Compliance Policy Guide recently issued on compounding medications for animals which disallows all compounding from bilk pharmaceutical ingredients.

The requirements of this CG are very problematic and a comment period was not allowed before these were put into effect. This is in violation of the FDA Good Guidance Practices.

It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances. There are numerous instances where the animal would have not survived without assistance from special made medications. These regulations are more stringent than what can be made for humans and I ask that you please reconsider this action which will put our pets at a great disadvantage.

Sincerely,

Sharlea M. Leatherwood, P.D.

Pharmacist and President

Valley Prescription Services, Inc.

Cc: Representative Sam Graves Commissioner Mark McClellan

03/30/4043 03.13 1101031000

September 30, 2003

Dr. Stephen Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855

I am a Compounding Pharmacist who specializes in Veterinary Pharmacy. As such, my client's owners have told me that I have saved the lives of their pets by making medicinals that increase compliance from their pets due to palatability. I want to continue to save the animals.

The Compliance Policy Guide (CPG), which was issued by CVM, was put in final form without allowing opportunity for comments. This is in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect. Pharmacists, as well as pet-owners and veterinarians are greatly affected and would have spoken out regarding the benefits of Compounding Pharmacists compounding from bulk active pharmaccuticals.

FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances. In just one specific example, I was able to compound Diazoxide Suspension for a dog that had an insulinoma at an affordable price by using bulk chemical as opposed to available capsules for compounding. I was able to flavor it suitably for a dog's taste to increase compliance and to concentrate it properly so that the dog could manage the size of the dose. The pet owners credited me for giving them time with their pet that they would not otherwise have had since he was able to get his medicine and extend his life.

I am requesting that the FDA withdraw the Compliance Policy Guide and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Virginia Wenzel, R.Ph.

Wirginia Precyc, RPL Supervising Pharmacist

Royal Compounding Pharmacy

359 Flatbush Ave, Brooklyn, N.Y. 11238

Phone: (718) 783-3100 Fax: (718) 783-1600 Email: <u>KingsRx1@aol.com</u>

"cc: Mark McClellan, FDA Commissioner; cc: President Bush; cc: Sen. Schumer; cc:

Sen. Clinton; cc: Rep. McCarthy; cc: IACP."

To: Dr. Stephen Sundlof, Director

Center for Veterinary Medicine

U.S. Food and Drug Administration (HFV-1)

7500 Standish Place Rockville, MD 20855

September 30, 2003

14:52

Dear Dr. Sundlof,

In July 2003, the Center for Veterinary Medicine issued a Veterinary Compliance Policy Guide (CPG) in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this-CPG deserve a comment period before being put into effect.

FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that compounding pharmacists such as myself be allowed to compound for non-food producing animals from bulk drug substances, as many animals and their owners depend on these customized medications to prevent seizures, control diabetes and blood pressure, maintain bladder control, and much more. Our compounding laboratory contains equipment that can be used to prepare much more precise doses in palatable and/or cosmetically appealing dosage forms than can be compounded using traditional equipment like a mortar and pestle.

Please withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented. Thank you.

Sincerely,

Carl E. Shields, R.Ph.

The Medicine Shoppe 100 Liberty St. Clarion, PA 16214

Phone: 814-226-9310 Fax: 814-226-9329

E-mail: 1204@medicineshoppe.com

cc. Mark McClellan, MD, Ph.D., FDA Commissioner

Senator Arlen Specter
Senator Rick Santorum
Representative John Peterson
International Academy of Compounding Pharmacists

SEM ON ON THE LOG PETION CHIMINIO

BEACH Pharmacy Inc. HIGHWAY 90 @ TEGARDEN ROAD 757 16th Street Gulfport, MS 39507 (228) 896-7070

September 29, 2003

Dr. Stephen F. Sundlof, Director Center for Veterinary Medicine U. S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855

Dear Dr. Sundlof,

It has come to my attention that the CVM has issued a Compliance Policy Guide in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirement of this CPG are extremely problematic and deserve a comment period before being put into effect. It is essential that pharmacist be allowed to compound for non-food producing animals from bulk drug substances. We have 10 or 12 dogs that we compound Potassium Bromide solutions for to prevent seizures. The pets have not responded well to other manufacturers preparations and would probably die with out the Potassium Bromide prepared for bulk. There are no human preparations to make if from. This is just one example of many such cases.

Please consider withdrawing the CPG and reissue it in draft form to allow for pharmacist, veterinarians, and patients to comment on its provisions before it is implemented. Thank you in advance for your consideration.

Sincerely,

Larry A. Krohn R. Ph.

cc: Mark McClellan, FDA Commissioner Senator Thad Cochran

Senator Trent Lott

Congressman Gene Taylor

IACP

Davis Islands Pharmacy & Compounding Lab

232 E. Davis Blvd Tampa, FL 33606

October 1, 2003

Dr Stephen Sundiof, Director, Center for Veterinarian Medicine US Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD, 20855

Dear Dr. Sundlof,

Re: CVM CPG

This letter is to inform you of my concern with the Center for Veterinery Medicine's (CVM) Compliance Policy Guide (CPG). It has been brought to my attention that this was issued in final form without any opportunities for comments from pharmacists, veterinanans or patient owners, which is in violation of the FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into practice.

The FDA's prohibition of compounding from bulk active pharmaceutical ingredients is extremely problematic. It is essential that pharmaces be allowed to compound for non-food producing animals from bulk drug substances. Currently, by using bulk drug substances, we are able to provide quality, compounded medications, not only at affordable prices but also to owners who would other wise have no choice but to use medications that are not made for animals.

Your new policies would increase the price of medicines to animals by forcing both the compounding pharmacies and veterinarian to buy in small units, or by reducing competition by allowing only commercial manufacturers the ability to make medications for non-food producing animals (and the track records for such medications are abysmal- the manufacturers routinely drop production of veterinanan products.)

By enacting this CPG you are depriving the compounding pharmacy, as well as the veterinarians from an integral part of their practice, since in the state of Florida, veterinarians fall under the provisions of state pharmacy law when it comes to preparing medications from bulk drug substances for their patients. This would also deny and restrict a patient and owner the ability to freely choose to get their prescription filled at a local compounding pharmacy, as well as increasing the final price of any new medications. You are also denying veterinarians the choice of using unique medications and delivery systems that benefit their patients.

I ask the FDA withdraw the CPG and ressue 4-in draft form to allow pharmacists, veterinarians and patients and their owners to comment on its provisions before it is implemented. Thank you for your prompt attention to this matter.

Respectfully,

Michael W. Slone

Compounding Technician, Davis Islands Pharmacy

Comact: (813) 254-1888 Voice: (813) 254-8395 Fax: comphami@mindsping.com E-mell-

Cc. Mark McClellan, FDA Commissioner

Cc: Senator Bob Graham, Senator Bill Nelson, and Representative Jim Davis

Cc IACP

TOTOTOPHOLIC OTOTOPHOLOGIE

Long Island's Leading Compounding Pharmacy Ettinger Pharmacy

60 New Hyde Park Boad Garden City, New York 11530 Burton Ettinger B.S. Ph.

Tel (516) 437-0166

Fax (516) 437-0180

October 1, 2003

LIBORIO I BROTHE

Dr. Stephen F. Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855

Dear Dr. Sundlof;

One of the most essential areas of proscription compounding is in the practice of veterinary medicine. Each day veterinarians call on me to successfully prepare a unique and crucial preparation for one of their patients. Many of these prescriptions are lifesaving. Others provide comfort, relief of seizures, pain control, hormone therapy, chemotherapy and emotional stability that, only in the special dosage forms that I compound, will give an owner the ability to successfully dose and manage their animal's condition. We compound only for non-food animals, including birds, ferrets, reptiles, canines and felines. Quite simply, if I were unable to obtain and dispense the bulk pharmaceuticals that are required for these specialized medications, I would have to turn away 80-90% of the prescriptions written by the veterinarians I serve:

The Compliance Policy Guide issued by CVM without allowing opportunity for comments is inviolation of FDA Good Guidance Practices. Many requirements of this guide will create extreme difficulties for veterinary patients and therefore surely deserve a comment period before being put into effect. It is clear that in order to continue to meet the special needs of the veterinary patient and the veterinarian, bulk pharmaceuticals must be available to a compounding pharmacist. Before such a drastic step as is proposed in the guide is taken, common sense and concern for the many animals currently being successfully medicated should call for FDA to withdraw the CPG and reissue it in draft form. This will allow pharmacists, veterinarians, and patients to comment before it is implemented. I call on you to allow us to present our position and preserve the health of our patients.

Burton Etting

Burton Ettinger B.S. Ph.

cc:

Mark McClellan, FDA Commissioner Senator Hillary Clinton Senator Charles Schumer Rep. Carolyn McCarthy Rep. Pete King IACP



October 1, 2003

Dr. Stephen Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)7500 Standish Place
Rockville, MD 20855-

Dear Dr. Sundlof:

The U.S. Food and Drug Administration, Center for Veterinary Medicine recently issued a Compliance Policy Guide on compounding for animals that disallows all compounding from bulk pharmaceutical ingredients, a standard much more restrictive than FDA's policies governing compounding for human patients.

CVM issued this compliance policy guide (CPG) in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect.

FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances. At our pharmacy, we compound many different medications for cats and dogs from bulk chemicals to help with behavior problems, thyroid problems and hypertension, just to name a few.

I am asking FDA to withdraw the CPG and reissue it in draft form to pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

nt. Phan. D

Sincerely

Robert Quint, Pharm.D.

30100 Town Center Dr., #O-340

Laguna Niguel, CA 92677

Phone: (949) 642-0106, Email: costamesarx@yahoo.com

CC:

Mark McClellan, FDA Commissioner

Senator Feinstein Senator Boxer Representative Cox

I.A.C.P.

The Unique Care Pharmacy

275 Victoria Street • Sutte 1F • Costa Mesa, CA 92627 • (949) 642-0106 • (800) 564-1565 • FAX: (949) 642-5039

September 10, 2003

Dr. Stephen F. Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration(HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Stephen F. Sundlof,

I am writing to convey my concerns with the Compliance Policy Guide(CPG) issued that threatens my ability to compound many products for my veterinary patients. CVM issued this CPG in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect.

FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is <u>extremely problematic</u>. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

I want to ask FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Sincerely,

Dean A. Parker, RPH
Heritage Pharmacy
1507 Springhill Avenue
Mobile, AL 36604

(251)432-0718

ce: Mark McClellan, FDA Commisioner

cc: Representative Jo Bonner cc: Senator Jeff Sessions

cc: Senator Richard Shelby

cc: International Academy of Compounding Pharmacists

WOODS PHARMACY

OLD FASHION SODA FOUNTAIN

R PRESCRIPTION COMPOUNDING R

Dana L. Woods, P.D. Annette Woods 301 West Main P.O. Box 1229

Mountain View, Arkansas 72560

(870) 269-3253 1-800-653-8442 Home Phone:

Business Phones:

(870) 269-3121 email: danaw@mvtel.net OC 70 Ber 1, 2003

STEPHEN SUNDIOF Din. Courten for ULT Medicine at FBA

IN REGARDS TO THE COM Compliance Policy Gu.

(CPG) I have some Real concerns.

(CPG) I have some Real concerns.

Remember given on Opportunity To Comment on this. I wo leas some This is

NOT LOSATHY COLARGET. PRILIBITION IN this COL of compounding From Bulk For Non Food Animals is reply Krula 7 RRESPINSIBLE ON YOUR PARTS.

IT Would Be For Your Best interest & in the Best IN terest of the Worting Public to Be Able To Comm ON This CPA + maybe WOLK OUT A ROSSINGBLE FOR

Dann Work, Compounding PARRACIST

(C: MARK McCLellan, FDA Commissioner US Rep MARION BERRY 1-202 225 4076 FAX

US Scrifton: BLANCE LINCOLN + 202-228-1271 FAX US SCHANA: MARK PAYOR 1-202-228-6908 FAY 1-281-495-0602 FAX IACP

Dr. Stephen Sundlof, Director.
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1),
7500 Standish Place
Rockville, MD 20855.

Dear Dr. Sundlof:

My name is William O. Moore and I am a compounding pharmacist in Sinton, TX. I am writing to you because of concerns I have with the new Compliance Policy Guide (CPG) recently issued. CVM issued this Compliance Policy Guide in final formwithout allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect. FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

I am writing to ask the FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented. Please take these concerns of mine into consideration.

William O. Moore R.Ph.

101 W. Sinton Street

Sinton, TX 78387

800-734-2418

361-364-5028 (fax)

www.moorespharmacy.com

President

MOORES PHARMACY

WOM:lmm

cc: Mark McClellan, FDA Commissioner

Scn. Kay Bailey Hutchinson

Sen. John Cornyn

Rep. Ruben Hinojosa

LACP

Weylan McAnally, R.Ph Red Oak Drug, Inc. 106 E. Ovilla Rd, Suite 1 Red Oak, TX 75154 972-617-2222 972-617-6020 fax

Dr. Stephen Sundlof, Director Center for Veterinary Medicine US Food and Drug Administration 7500 Standish Place Rockville, MD 20855

Dr. Sundlof.

I am writing to express my concerns Compliance Policy Guide (CPG) recently issued by the Center for Veterinary Medicine. The CVM issued this CPG in final form without allowing opportunity for comments from veterinary practitioners or compounding pharmacists. This is direct violation of your own FDA Good Guidance Practices. I believe that imput from these professionals is essential to a sensible and comprehensive policy.

My second concern is the FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals. This provision is extremely problematic. This CPG would effectively kill several million companion animals. As an example, the main chemical used for urinary incontinence in canines would be unavailable for use. Without this chemical, millions of dogs would be "put to sleep" by their owners. This example is for just one chemical. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances. The vast majority of veterinary compounding is done for companion animals.

I request that you withdraw the CPG and reissue it in draft form to allow pharmacists; veterinarians and patients (pet owners) to comment on its provisions before it is implemented. In it's current form, the CPG would be extremely harmful to veterinarians and their patients.

Sincerely,

Weylan McAnally, R.Ph Red Oak Drug, Inc. Dr Stephen Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration (hfv-1) 7500 Standish Place Rockville, MD 20855-

Dr Sundlof,

I am concerned with the Compliance Policy Guidance issued by the CVM in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect. FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances. Without compounding, many of our pet conditions such as seizure disorders, thyroid disorders, diabetic complications, infections, etc can not be treated without compounding from bulk substances.

Thank you for your consideration it this important matter.

Sincerely,

Mary-Jo Roth R.Ph. 137 Meadow Hill Drive York, PA 17402

Fax 717-845-8767

Email brothmedshop@yahoo.com

Cc: Mark McClellan, FDA Commissioner;

yo Rothern

Cc: Representative Todd Platts; Rick Santorum; Arlen Spector;

Cc: IACP

300 N.Gun Barrel Lane Gun Barrel City, Tx 75156 October 2, 2003

Mark McClellan, MD FDA Commissioner Rockville, MD

Dear Dr. McClellan:

As a Pharmacist, I wish to voice my concern for the Compliance Policy Guide the Center for Veterinary Medicine has issued. The CVM issued this guide in its final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect.

FDA's prohibition in this CFG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances. I have "patients"—dogs, cats and birds—who would die without the medication I presently compound for them.

Please ask the FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and owners of pets to comment on its provisions before it is implemented.

B. Cova, Rth

Thank you for your consideration.

Sincerely,

Marion B. Cobb, RPH Gun Barrel City Pharmacy

gbcrx1@aol.com

cc: Rep. Jeb Hensarling
Sen. Kay Bailey Hutchison
Sen. John Cornyn

IACP



Dr. Steven Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855

October 1, 2003

Dear Dr. Sundiof,

37985

HAMILTON COURT

SUITE G-200

FARMINGTON MILLS,

#1 (8334

E 248, 489, 1573

248 | 489 | 1586

t are writing today to express my concern with the new Compliance Policy Guide (CPG) issued by FDA regarding prescription compounding from bulk chemicals for non-food producing animals.

Particularly, I am concerned that this CPG was issued in violation of FDA Good Guidance Practices, without allowing opportunity for public comment. There are a variety of issues in this CPG that are cause for concern and deserve a proper comment period.

My primary concerns are:

First. incuted do veterinariens, pet owners, and pets across the country rely on the delivery of high quality pharmacauthaja formulated from ours, some constructions from bulk materials are many restricting veterinary access to bulk materials and out to coupe disruptions in the ability of veterinarians, pharmacists, and pet owners to provide quality care.

Second, the use of pure medications for the formulation of themselves in the second well established practice. Qualit not due their to have access to prescriptions for the same from making metables to have access to prescriptions sources of drug confound the formulation present and make contain dosage forms.

fully considered by communication with the current and control of the CPG must be

I respectfully ask you to withdraw the CPG and reference in a resource of the votoriorisms observations and patients to commont before implementation.

Sincerely:

Scott Popyk, RPh, FIACP

Director

Health Dimensions, Inc.

248-489-1573

cc: Mark McClellan, FDA Commissioner, Sen. Levin, Sen. Stabenow, Rep. McCotter

MULBERRY PHARMACY INC.

1009 NORTH CHURCH PO BOX 767
MULBERRY, PL 33860

(\$63) 425-1101 (VOICE) (\$63) 425-2802 (FAX)

NOTICE:

THIS MESSAGE IS INTENDED FOR THE USE OF INDIVIDUAL OR ENTITY TO WHICH IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PREIVILEGED, CONFIDENTIAL AND EXEMPT FROM DISCLOSURE UNDER APPLICABLE LAW:

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FACSIMILE TRANSMITTAL SHEET	
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PHONE NUMBER:	SENDER'S REFERENCE NUMBER:
RE:	Your reference number:
NOTES/COMMENTS:	ease comment Oplease reply Oplease recycle
Just anothe air for destroy co Rep Putnam's to a hierd of v	thept by the manufacturity apounding. I happen to know family - his older broth is more ince 2nd grade



Dan Fucarino, R.Ph. Christi Griffith Pharm. D. Michelle Alfonso Pharm. D.

Compounding Pharmacists

& Compounding Center

10205 Lake Carroll Way Tampa, FL 33618 PHONE-\$13-961-8798 PAX-813-962-0092

Dr. Steven Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855

Dear Dr. Sundiof,

I am very concerned about the Compliance Policy Guide (CPG) in final form without giving the opportunity to comment. This is a violation of the FDA Good Guidance Practices. I believe that there some problematic requirements and would like the opportunity (as the law provides) to comment before the law goes into effect.

The FDA's prohibition in the CPG against compounding from bulk chemical is extremely problematic! It is essential that pharmacist be allowed to compound for non-food producing animals from bulk chemicals,. I have hundreds of patients that rely on my provision of critical medications to sustain their life. Ex. Felines-methimazole, amitripyline, prednisolone etc.

Canines- potassium bromide, azathiaprine, mitotane, piroxicam etc.

I would kindly request that you withdraw the CPG and reissue it in draft form to allow pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Respectfully Yours.

Dala Fucarino RPh

President Carrollwood Pharmacy

Phone 813-961-98798 Fax- 813-961-8798cwrx@tampabay.rr.com

CC: Mark McClellan M.D. Ph. D.

Sen. Bob Grahan
Sen Bill-Nelson
Rep. Jim Davis
Rep. Mike Bilirakis
Dr. Michael Chaddock AVMA

28/-495-CGOL



& Compounding Center

Dan Fucarino, R.Ph. Christi Griffith Pharm. D. Michelle Alfonso Pharm. D.

Compounding Pharmacists

10205 Lake Carroll Way Tampa, FL 33618 PHONE-813-961-8798 FAX-813-962-0092

This is an example of the letters I sent to the vets and to the FDA.

Thanks

Dan Fucarino RPh



Dan Fucarino, R.Ph. Christi Griffith Pharm. D. Michelle Alfonso Pharm. D.

Compounding Pharmacists

10205 Lake Carroll Way Tampa, FL 33618 PHONE- 813-961-8798 FAX-813-962-0092

Dear Veterinarian.

& Compounding Center

Over the years you have been kind enough to send me numerous patients to get compounded medications using bulk chemicals. Unfortunately the FDA is about to severely limit our ability to treat your patients. It is very important to read the information below to help us keep our right to treat these patients. I am asking you to do a few things, but most importantly, to write to the FDA. We ask you to fax this letter to the AVMA, your Senators and Representatives. All the important numbers are listed below. Please ask every veterinarian and staff member to send the same or similar letters. We need numbers!

Also, if possible, we would like for you to ask you clients to write also. I have included all information below and on the following pages. Thank youyou're your concern and help: Please read the information below.

ACTION PLAN

1. Write a letter and fax to:

2. Dr. Steven Sundiof, Director

Center for Veterinary Medicine

U.S. Food and Drug Administration (HFV-1)

7500 Standish Place

Rockville, MD 20855

- (2) List your concerns with the guidance. Keep in mind that your letter does not need to be very long. Please include the following statements:
- (a) CVM issued this Compliance Policy Guide (CPG) in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect.
- (b) FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances. (You may provide examples of how this restriction would affect your veterinary patients. Be sure to use only non-food producing animals as examples.)

- X.
- (3) End your letter by asking FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.
- (4) Sign the letter with your name, title, address, and contact information (i.e. phone fax, email).

PLEASE DON'T FORGET THIS PART- IT'S VERY IMPORTANT

(5) Below your signature, include the following" "cc: Mark McClellan, FDA Commissioner; cc: [your Senators and Representative] (see list below)

FAX THIS LETTER TO:

- 1. STEVEN SUNLOF (301) 827-4401
- 2. FDA Commisioner Mark McClellan M.D., Ph.D. (301)443-3100
- 3. Fax a copy to the AVMA Attn: Michael Chaddock (director of Government regulations) Fax- 202-842-4360

FAX TO:

Senator Bob Graham Fax: (202) 224-2237 or e-mail www. graham.senate.gov
Senator Bill Nelson Fax: (202) 228-2183 or e-mail www.billnelson. Senate.gov
Rep. Jim Davis Fax; (202) 225-5652 or e-mail www.house.gov/jimdavis
Rep. Mike Bilirakis Fax: (202) 225-4085 or e-mail www.house.gov.bilirakis

4. Post a sign in you reception area (enclosed). Ask your patients to fill out the form I've included and fax this letter to the FDA @ 301-827-4401 (number is on the template)

Please know that I appreciate any and all efforts that you make to this end. I appreciate all the you have done for me in the past. I hope that by doing this we can preserve our ability to provide the best possible therapy to our patients!

Thank You.

Dan Fucarino, R.Ph.

To: Dr. Stephen Sundlof, Director Center for Veterinary Medicine

U.S. Food and Drug Administration (HFV-1)

7500 Standish Place Rockville, MD 20855

September 30, 2003

Dear Dr. Sundlof,

In July 2003, the Center for Veterinary Medicine has issued a Veterinary Compliance Policy Guide (CPG) in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG deserve a comment period before being put into effect.

FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances, as many animals and their owners depend on these customized medications to sustain the animal's life.

Please withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Sincerely,

Patricia L. Storey, R.Ph.

Phone: 814-337-2509 Fax: 814-336-5225 19487 East Cole Rd. • Meadville, PA 16335 USA

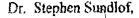
E-mail: patti@storeymarketing.com

Patrices 2 Story R. Pt.

cc: Mark McClellan, MD, Ph.D., FDA Commissioner

Senator Arlen Specter
Senator Rick Santorum
Representative Philip English

International Academy of Compounding Pharmacists



The CVM issued this Compliance Policy Guide in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect:

The FDA's prohibition in this CGP against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances. What are we supposed to tell our customers who get prescriptions for their cats or dogs? These are people whose pets are members of their families. We compound Potassium Bromide for dogs with seizures, and Methimazole for cats with thyroid disorders, just to mention a few cases.

We are asking the FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Thank you for your time in reviewing this matter.

O'Connor Pharmacy Inc. Staff Tim O'Connor D. Ph. 1113 E. Hartford Ponca City, OK 74601 (580) 765-3055

cc: Steven Sundlof---(301) 827-4401.

FDA Commissioner Mark McClellan, MD Ph.D--(301)443-3160.

Sen Nickles---(405) 231-4941.

Sen Inhofe-----(918) 748-5111.

Rep Lucas-----(405) 373-1958.



Professional PHARMACY & COMPOUNDING LAB

October 1, 2003

Dr. Stephen Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855

Dear Dr. Sundlof:

Recently the CVM issued a Compliance Policy Guide (CPG) in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect.

The FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances. Nearly all of our compounds are created for veterinary patients using bulk chemicals, which rely on our expertise to compound them into alternate dosage forms & palatable prescriptions. Without the use of bulk chemicals, we will have minimum patient compliance resulting in inadequate therapy or possibly death.

We are asking you to withdraw the CPG and reissue it in draft form to allow pharmacists, veterinarians, and patients to comment on its provisions before it is implemented. Thank you for your time.

Sincerely,

Richard P. Brisson, R.Ph.

Compounding Pharmacist/Owner

Jennifer Cunha, R.Ph.

Compounding Pharmacist

Cc: Mark McClellan, FDA Commissioner

Senator Edward Kennedy

Senator John Kerry

Representative Barney Frank

International Academy of Compounding Pharmacists

American College of Veterinary Pharmacists

American Veterinary Medical Association

458 Dartmouth Street, New Bedford, MA 02740
Phone (508) 996-3778 • Fax (508) 996-3779
Toll Free: 1-888-RXO-RXRX • Toll Free Fax: 1-888-584-6337





Sarasota's Original Compounding Pharmacv.

September 30, 2003

Dr. Stephen F. Sundlof, Director. Center for Veterinary Medicine U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855.

Dear Dr. Sundlof:

I am Fred Kinnard, R.Ph. and have owned Kinnard's Compounding Pharmacy in Sarasota since 1968. 1 have been compounding medication for household pets all of these years and feel that the discontinuance of bulk chemicals may cause severe hardship or death to many of these animals. I certainly understand that these chemicals should not be introduced into the food supply through farm animals.

I feel CVM issued this Compliance Policy Guide in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect. I also feel the FDA's prohibition in this CPG against compounding from bulk active pharmacouticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

I would ask the FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented. We need a working community standard that patients, professionals, and administrations can implement that is not detrimental to the patient and will provide improved efficacy for all involved.

Sincerely, Fred a Kinnand

Fred A. Kinnard, R.Ph.

Compounding pharmacist (FL Lic#10873)

7654 Cove Terrace Sarasota, FL. 34231

I wonted you to be awarlopman Phone: 941-922-3428(H) 941-366-0880(W) 941-366-4977(Fax)

o-mail: mdlcomp@mindspring com cc: Mark McClellan, FDA Commissioner

cc: Senator Bob Graham

cc: Senator Bill Nelson

cc: Representative Katherine Harris

cc IACP

I wanted you to be aware of these recent development

September 30, 2003

Dr. Stephen F. Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD, 20855

Dear Dr. Sundlof:

My name is Jay Swick and I'm a compounding pharmacist in Sarasota, FL. I am very concerned about my ability to use bulk drug substances to compound unique medication formulas and delivery methods that are critical to the well being of my customers and their pets. Without bulk drug substances to prepare these very customized treatments for these animal patients, many pets will be subject to undue suffering with detrimental effects to their health as well as to the health of the owners who love and cherish them. Many times a pet is the "significant other" in some person's life.

I feel CVM issued this Compliance Policy Guide in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect. I also feel the FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

I would ask the FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented. We need a working community standard that patients, professionals, and administrations can implement that is not detrimental to the patient and improved efficacy for all involved.

Sincerely,

Jay A Swick R-Ph.

Compounding pharmacist (FL Lic#12739, IN Lic#12560)

7661 Cove Terrace Sarasota, FL. 34231

Phone: 941-925-7661(H) 941-366-0880(W)941-321-9001(Cell)941-924-7626(Fax)

e-mail: jswick1@comcast.net

cc: Mark McClellan, FDA Commissioner

cc: Senator Bob Graham cc: Senator Bill Nelson

cc: Representative Katherine Harris

cc: IACP



9/30/03

"Solving Problems with Custom Medications"

Dr. Stephen Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1):
7500 Standish Place
Rockville MD 20855

Dear Dr. Sundlof:

I would like to voice my displeasure that CVM issued the Compliance Policy Guide in final form without allowing opportunity for comments. FDA's prohibition in this CPG against compounding from bulk chemicals lacks common sense. Dogs, cats, and other domestic pets have benefited greatly by compounding pharmacists preparing custom medications. Their quality of life has been enhanced, owners have been pleased, and no harm has come from it. It is hard to imagine that we prepare many compounded prescriptions for our human patients, including hormones, where patients have enjoyed life like neverbefore, and the CPG would forbid us from helping non-food producing animals. I fail to see a negative side to this, especially in light of the fact that many manufacturers have discontinued making medications because they are not able to make enough money at it, while we can make those same formulas that have worked well for veterinarians.

Please withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions <u>before</u> it is implemented.

Sincerely,

Dale L. Bartel, R.P.

Del Barts

cc. Mark McClellan MD, Senator Tom Harkin Senator Charles Grassley Representative Steve King

Bandy's Pharmacy, Inc PO Box 546 Salem, IL 62881 618-548-4000

Dr. Stephen Sundlof, Director Center for Veterinary Medicine. U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855

Dean Sir:

I am writing concerning the implementation of the compliance policy guide in the final form, which regulates the compounding from bulk drug substances for veterinary use.

The lack of input and comments on the CPG from concerned parties is in violation of the FDA Good Guidance Practices, and I am asking for you to reverse this decision and allow comment.

The CVM issued the Compliance Policy Guide (CPG) in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect.

The FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

We have several veterinarians who order prescriptions for non-food producing animals that we compound from bulk drug substances. These include, but are not limited to, urinary products, seizure products, blood pressure products, and antibiotic products.

I am asking that the FDA withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Thank You,

Eric S. Bandy, RPh Phone 618-548-4000 Fax 618-548-3784 E-Mail ericbandy@hotmail.com

cc: Mark McClellan, FDA Commissioner

cc: Senator Peter Fitzgerald cc: Senator Richard Durbin

cc: Representative John Shimkus

cc: IACP

Bandy's Pharmacy, Inc PO Box 546 Salem, IL 62881 618-548-4000

Dr. Stephen Sundlof, Director Center for Veterinary Medicine, U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855

Dear Sir:

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I am asking that the FDA withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Thank You,

Steven L. Bandy, RPh Phone 618-548-4000 Fax 618-548-3784 E-Mail bandy@midwest.net

cc: Mark McClellan, FDA Commissioner

cc: Senator Peter Fitzgerald

cc: Senator Richard Durbin

cc: Representative John Shimkus

cc: IACP

Greenpark Pharmacy

7515 S. Main #150 Houston, TX 77030 713.795.5812 knhughes20@aol.com

September 30, 2003

Dr. Stephen Sundlof: Director-Center for Veterinary Medicine U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855

Dear Sir:

Land many of the Veterinary Doctors we compound medications for have a real problem with the new compliance guide. CVM issued this compliance policy guide (CPG) in final form without allowing comments. Not allowing comments is a violation of FDA. Good. Guidance Practices. Many requirements of the CPG are extremely problematic and deserve a comment period before being put into effect.

FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals has many problems. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk substances. I have numerous dogs, that we provide phenylpropanolamine for Phenylpropanolamine is no longer only available commercially, only in bulk form as well as many other chemicals including Cyclosporin.

Please withdraw the CPG and reissue it in draft form to allow for pharmacist, veterinarians; and non-food producing animal owners to comment on its provisions before it is implemented.

Sincerely,

Kenneth Hughes, RFh

Owner

cc: Mark McClellan, FDA Commissioner Sen. John Cornyr. - Texas-Sen. You Belley Marketings. - Texas

Sen Kay Bailey Hutchison - Texas

Rep. Chris Bell Texas

I wanted to of this you aware development gecent development

Dr. Stephen Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855

Dear Dr. Sundlof:

My name is Don D. Bristow and I am a compounding pharmacist in Sinton, TX: I am writing to you because of concerns I have with the new Compliance Policy Guide (CPG) recently issued. CVM issued this Compliance Policy Guide in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect. FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for <u>non-food</u> producing animals from bulk drug substances.

I am writing to ask the FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented. Please take these concerns of mine into consideration.

Don D. Bristow, R.Ph.

101 W. Sinton Street Sinton, TX 78387:

800-734-2418

361-364-5028 (fax)

www.moorespharmacy.com

Vice-President

MOORES PHARMACY

DDB:lmm

cc: Mark McClellan, FDA Commissioner

Sen. Kay Bailey Hutchinson

Sen. John Cornyn

Rep. Ruben Hinojosa

IACP

10/1/2003

Dr. Stephen Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration (HFV 1) 7500 Standish Place Rockville, MD 20855

Dear Dr. Sundlof,

My name is Jim Clark and I am a compounding pharmacist in Beeville, TX. I am writing to you because of concerns I have with the new Compliance Policy Guide (CPG) recently issued. CVM issued this Compliance Policy Guide in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices: Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect. FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

I am writing to ask the FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented. Please take these concerns of mine into consideration.

Jim Clark R.Ph.

1000 E Houston

Beeville TX 78102

800-734-2417

361-362-1537 (fax)

moorescitydrug@bcni.net

Vice-president

MOORES PHARMACY

Rnm

cc: Mark McClellan, FDA Commissioner

Sen. Kay Bailey Hutchinson.

Sen. John Cornyn Rep. Ruben Hinojosa

IACP

10/1/2003

Dr. Stephen Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof.

My name is Robert Moore and I am a compounding pharmacist in Beeville, TX. I am writing to you because of concerns I have with the new Compliance Policy Guide (CPG) recently issued. CVM issued this Compliance Policy Guide in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect. FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

I am writing to ask the FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented. Please take these concerns of mine into consideration.

Robert Neal Moore R.Ph.

Just N Mar

1000 E Houston Beeville TX 78102 800-734-2417

361-362-1537 (fax)

moorescitydrug@beni.net

Vice-president

MOORES PHARMACY

Rnm

cc: Mark McClellan, FDA Commissioner

Sen. Kay Bailey Hutchinson.

Sen. John Cornyn Rep. Ruben Hinojosa

IACP



700 Avenue D Snehomish, VA 98290 Phone: 360-568-7787 Fax: 360-568-3626 www.kuslatabharmacv.com

October 1, 2003

Dr. Stephen Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration (HFV-1) 7500 Standish Place

Dear Dr. Sundlof,

Rockville, MD 20855

I wanted to make you aware of this recent development.

Dawn I psen

I'm writing in regards to the Guidance for FDA Staff and Industry, Compliance Policy Guides Manual, Sec. 608.400; Compounding of drugs for use in animals. The Center for Veterinary Medicine issued this Compliance Policy Guide (CPG) in final form without allowing opportunity for comments. This action is in violation of the FDA Good Guidance Practices. Many of the requirements of this stated CPG are extremely problematic and deserve a comment period before being finalized.

The FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is not practical and is unethical, as it will deny family pets of medications and treatment options, which would normally be available. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

I ask that the FDA withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Sincerely,

Dawn Ipsen, PharmD

Compounding Pharmacist

Kusler's Pharmacy

700 Avenue D

Snohomish, WA 98290

Phone (360) 568-7787

Fex (360) 568-3626

E-mail dawnipsen@yshdo.com

cc: Mark McClellan, FDA Commissioner

Senator Patty Murray
Senator Maria Cantwell

Representative Jay Insiee Representative Rick Larsen

International Acedemy of Compounding Pharmacists

414 S.W. 6th St. - Grants Pass, OR 97526 - (503) 476-4262

October 1, 2003

Dr. Stephen Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855

Sir:

The recent restrictive, arbitrary & harmful issuing by CVM of the Compliance Policy Guide (CPG) for Veterinary Compounding in final form without allowing opportunity for comments is in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect.

FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances. Many, many of our veterinary patients would no longer have vital medications available for their animals if this rule goes into effect without proper comment and evaluation periods.

I would ask that the FDA withdraw this CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before being implemented.

Respectfully.

Michael F Maifett, R. Ph//President

Grants Pass Pharmacy 414 SW 6th Street

Grants Pass, Oregon 97526

Phone: 541-476-4262 FAX: 541-474-1443

cc: Mark McClellan, FDA Commissioner

Sen. Ron Wyden, Oregon

Sen. Gordon Smith, Oregon-

Rep. Greg Walden, Oregon

Rep. Peter DeFazio, Oregon

Subject: Veterinary Pharmaceutical Compounding

Dear Steven Sundlof, FDA Director.

The Center for Veterinary Medicine, U.S. FDA has issued a Compliance Policy Guide which threatens the pharmacists ability to formulate many medications for veterinary patients (pets).

CVM issued this CPG in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of the CPG are extremely problematic and deserve a comment period before being put into effect.

FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

Please withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and owners of pets who need alternative treatment options to comment on its provisions before it is implemented:

Respectfully.

Melissa Frederick

Compounding Technician

Melina A Fredrick

Professional Arts Pharmacy

Prescription Compounding Specialist

Eric Vidrine, P.D. F.A C.A.

Mandie Romero, P.D.

Germaine Robinson, R.Ph David Mayer, P.D.

Kevin LaGrange, R.Ph Lynn Darby, P.D.

October 15, 2003

Subject: Veterinary Pharmaceutical Compounding

Dear Steven Sundlof, FDA Director,

The Center for Veterinary Medicine, U.S. FDA has issued a Compliance Policy Guide which threatens the pharmacists ability to formulate many medications for veterinary patients (pets).

Oct. 16 2005 05:16PM P1 FAX ND.: 3379919844

FROM: PROARTSPHARMACY



Professional Arts Pharmacy

Presemption Compounding Specialist

Enc Vidime, PD FACA Mundie Romero PD Germaine Robinson, R.Ph David Maver, P.D. Kevin LaCirange, R.Ph Lynn Darby, PD

October 15, 2003

Subject: Veterinary Pharmaceutical Compounding-

Dear Steven Sundlof, FDA Director:

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Please withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and owners of pets who need alternative treatment options to comment on its provisions before it is implemented.

Respectfully.

my Vischler

Compounding Technician

cc: Mark McClellan, M.D. Ph.D. FDA Commissioner at 301-443-3100

cc: IACP at 281-495-0602

cc: Representative Chris John

cc: Senator John Breaux

cc: Representative Billy Tauzin

cc: Senator Mary Landrieu

cc: Representative David Vitter-

cc: Representative Richard Baker

620 Guilbeau Rd., Ste. A · Lafayette, LA 70506 · Ph. 337-991-0101 1-888-237-4737 · Fx. 337-991-0151

FROM: PPDARTSPHARMACY FAX ND.: 3379919844 Dct. 16 2003 03:17PM P2



Professional Arts Pharmacy

Prescription Commounding Specialist

Germaine Robinson, R.Ph. David Moyer, P.D. Kevin LiGrange, R.Ph. Lynn Darby, P.D.

October 15, 2003

Subject: Veterinary Pharmaceutical Compounding

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Respectfully,

Tina Dupuis

1ma

Compounding Technician

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cc: IACP at 281-495-0602

cc: Representative Chris John

cc: Senator John Breaux cc: Senator Mary Landrieu

cc: Representative Billy Tauzin cc: Representative David Vitter

CO. Ochacor Wary Lan

cc: Representative Richard Baker

620 Guilbeau Rd., Stc. A · Lafayette, LA 70506 - Ph. 337-991-0101 1-888-237-4737 - Fx. 337-991-0151

FAX ND. : 3379919844 Oct. 16 2003 03:17PM P3

-POM: PROARTSPHARMACY



Professional Arts Pharmacy

Prescription Compounding Specialist

Fric Vidrine, P.D. F.A.C.A. Mandie Romero, P.D. Germaine Robinson, R.Ph. David Mayer, P.D. Kevin LaGrange, R.Ph. Lynn Darby, P.D.

October 15, 2003

Subject: Veterinary Pharmaceutical Compounding-

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Respectfully,

Quanjalla/Cross

Compounding Technician

cc: Mark McClellan, M.D. Ph.D. FDA Commissioner at 301-443-3100-

cc: IACP at 281-495-0602

cc: Representative Chris John

cc: Senator John Breaux

cc: Representative Billy Tauzin

cc: Senator Mary Landrieu

cc: Representative David Vitter

cc: Representative Richard Baker

620 Guilbeau Rd., Ste. A · Lafayette; LA 70506 · Ph. 337-991-0101 1-888-237-4737 · Fx. 337-991-0151

FROM: PROARTSPHARMACY



Professional Arts Pharmacy

Prescoption Compounding Specialist

Germane Robinson, R.Ph. David Mayer, P.D. Keym LaGrange, R.Ph. Lynn Darby, P.D.

October 15, 2003

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Respectfully

Steven Carroll

Compounding Technician

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cc: IACP at 281-495-0602

cc: Representative Chris John

cc: Senator John Breaux

cc: Representative Billy Tauzin

cc: Senator Mary Landrieu

cc: Representative David Vitter

cc: Representative Richard Baker

620 Guilbeau Rd., Stc. A · Lafayerte, LA 70506 · Ph. 337-991-0101 1-888-237-4737 · Fx. 337-991-0151

FROM: PROARTSPHARMACY

FHX NU.: 3379919844



Professional Arts Pharmacy

Prescription Compounding Specialist

Eric Vidrine, P.D. F.A. C., A. Mandae Romero, P.D. Germaine Robinson, R.Ph. David Mayer, P.D. Kavin LaGrange, R.Ph. Lynn Darby, P.D.

October 15, 2003

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Respectfully

Mervin Benoit Delivery Driver

cc: Mark McClellan, M.D. Ph.D. FDA Commissioner at 301-443-3100

cc: IACP at 281-495-0602

cc: Representative Chris John cc: Representative Billy Tauzin

cc: Senator John Breaux cc: Senator Mary Landrieu

cc: Representative David Vitter

cc: Representative Richard Baker

620 Guilbeau Rd., Stc. A · Lafayette, LA 70506 · Ph. 337-991-0101 1-888-237-4737 · Fx. 337-991-0151



Professional Arts Pharmacy

Prescription Compounding Specialist

Germaine Robinson, R. Ph. David Mayer, P.D. Kevin LaGrange, R. Ph. Lynn Darby, P.D.

October 15, 2003

Subject: Veterinary Pharmaceutical Compounding

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Respectfully.

Kim LaFleur

Compounding Technician

cc: Mark McClellan, M.D. Ph.D. FDA Commissioner at 301-443-3100

cc: IACP at 281-495-0602

cc: Representative Chris John cc: Representative Billy Tauzin

cc: Senator John Breaux cc: Senator Mary Landrieù

cc: Representative David Vitter

cc: Representative Richard Baker

620 Guilbeau Rd., Ste. A - Lafayette, LA 70506 - Ph. 337-991-0101 1-888-237-4737 - Fx. 337-991-0151



Professional Arts Pharmacy

Prescription Compounding Specialist

Germaine Robinson, R.Ph. David Mayer, P.D.
Kevin LaGrange, R.Ph. Lynn Darby, P.D.

October 15, 2003

Subject: Veterinary Pharmaceutical Compounding

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Respectfully,

Leah Alborado, P.D.

Pharmacist

cc: Mark McClellan, M.D. Ph.D. FDA Commissioner at 301-443-3100

cc: IACP at 281-495-0602

cc: Representative Chris John

cc: Senator John Breaux

cc: Representative Billy Tauzin

cc: Senator Mary Landrieu

cc: Representative David Vitter

cc: Representative Richard Baker

Wharado

620 Guilheau Rd., Ste. A - Lafayette, LA 70506 · Ph. 337-991-0101 1-888-237-4737 · Fx. 337-991-0151

FAX NO. : 3379919844



Professional Arts Pharmacy Prescription Compounding Specialist

Eric Vidring, P.D. F.A. C.A. Mandie Romero, P.D. Germaine Robinson, R-Ph David Mayer, Pt. Kevin LaGrange, R.Ph. Lynn Derby, P.D.

October 15, 2003

FROM: PROARTSPHARMACY

Subject: Veterinary Pharmaceutical Compounding

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Compounding Technician

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cc: IACP at 281-495-0602

cc: Representative Chris John

cc: Senator John Breaux

cc: Representative Billy Tauzin

cc: Senator Mary Landrieu

cc: Representative David Vitter

cc: Representative Richard Baker

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Oct. 16 2003 03:21PM P9

TROM : PROARTSPHARMACY

FAX NO.: 3379919844



Professional Arts Pharmacy

Prescription Compounding Specialist

Eric Vulrine, P.D. F.A.C.A. Mandie Romero, P.D. Germaine Robinson, R.Ph. David Mayer, P.D. Kevin LaGrange, R.Ph. Lynn Darby, P.D.

October 15, 2003

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Respectfully

Kevin Lagrange,

Pharmacist

cc: Mark McClellan, M.D. Ph.D. FDA Commissioner at 301-443-3100

cc: IACP at 281-495-0602

cc: Representative Chris John

cc: Senator John Breaux

cc: Representative Billy Tauzin

cc: Senator Mary Landrièu

cc: Representative David Vitter

cc: Representative Richard Baker

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Professional Arts Pharmacy

Prescription Compounding Specialist

Enc Vubrue, P.D. F.A.C. A. Mandie Romero, P.D. Germaine Robinson, R-Ph. David Mayer; P-D. Kevin LaGrange, R.Ph. Lynn Darby, P.D...

October 15, 2003

Subject: Veterinary Pharmaceutical Compounding

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Respectfully,

Mona Bourgue

Receptionist

cc: Mark McClellan, M.D. Ph.D. FDA Commissioner at 301-443-3100

cc: IACP at 281-495-0602.

cc: Representative Chris John cc: Representative Billy Tauzin

cc: Senator John Breaux cc: Senator Mary Landrieu

cc: Representative David Vitter

cc: Representative Richard Baker

620 Guilheau Rd., Ste. A - Lafayette, LA 70506 - Ph. 337-991-0101 1-888-237-4737. Fx. 337-991-0154

FAX NO.: 3379919844 Oct. 16 2003 03:22PM P11

FROM: PROARTSPHARMACY



Professional Arts Pharmacy

Prescription Compounding Specialist

Eric Vidinie, P.D. F.A.C. A. Mandie Romero, P.D. Germaine Robinson, R.Ph. David Mayer, P.D. Kevin LaGrange, R.Ph. Lynn Darby, P.D.

October 15, 2003

Subject: Veterinary Pharmaceutical Compounding

Dear Steven Sundlof, FDA Director,

The Center for Veterinary Medicine, U.S. FDA has issued a Compliance Policy Guide which threatens the pharmacists ability to formulate many medications for veterinary patients (pets).

CVM issued this CPG in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of the CPG are extremely problematic and deserve a comment period before being put into effect.

FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

Please withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and owners of pets who need alternative treatment options to comment on its provisions before it is implemented.

Respectfully,

John Breaux

Delivery Driver

cc: Mark McClellan, M.D. Ph.D. FDA Commissioner at 301-443-3100

cc: IACP at 281-495-0602

cc: Representative Chris John cc: Representative Billy Tauzin

cc: Senator John Breaux cc: Senator Mary Landrieu

cc: Representative David Vitter cc: Representative Richard Baker

620 Guilbeau Rd., Ste. A - Lafayette, LA 70506 - Ph. 337-991-0101 1-888-237-4737 - Fx. 337-991-0151

Oct. 16 2003 03:23PM P12

FROM: PROARTSPHARMACY

FAX ND.: 3379919844



Professional Arts Pharmacy

Prescription Compounding Specialist

Eric Vulrine, P.D. F.A.C. A. Mandie Romero, P.D. Germaine Robinson, R.Ph. David Mayer, P.D. Kevin LaGrange, R.Ph. Lynn Darby, P.D.

October 15, 2003

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Please withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and owners of pets who need alternative treatment options to comment on its provisions before it is implemented:

Respectfully,

Debbie Bue Bookkeeper

cc: Mark McClellan, M.D. Ph.D. FDA Commissioner at 301-443-3100

cc: IACP at 281-495-0602

cc: Representative Chris John

cc: Senator John Breaux cc: Senator Mary Landrieu

cc: Representative Billy Tauzincc: Representative David Vitter

cc: Representative Richard Baker

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Oct. 16 2003 03:24PM P13

FAX ND. : 3379919844



Professional Arts Pharmacy

Prescription Compounding Specialist

Fric Vidine, P.D. F.A.C.A. Mandie Romero, P.D. Germaine Robinson, R.Ph. David Mayer, P.D. Kevin LaGrange, R.Ph. Lynn Darby, P.D.

October 15, 2003

FROM: PROARTSPHARMACY

Subject: Veterinary Pharmaceutical Compounding

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Respectfully.

Karee Briggs

Compounding Technician

cc: Mark McClellan, M.D. Ph.D. FDA Commissioner at 301-443-3100

cc: IACP at 281-495-0602

cc: Representative Chris John

cc: Senator John Breaux

cc: Representative Billy Tauzin-

cc: Senator Mary Landrieu

cc: Representative David Vitter

cc: Representative Richard Baker

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Oct. 16 2003 03:24PM P14

FROM : PROARTSPHARMACY



FAX ND. : 3379919844

Professional Arts Pharmacy

Pre-caption Compounding Specialist

Eric Vidrine, P.D. F.A.C.A. Mandie Romero, P.D. Germaine Robinson, R.Ph. David Mayer, P.D. Kevin LaGrange, R.Ph. Lynn Darby, P.D.

October 15, 2003

Subject: Veterinary Pharmaceutical Compounding

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Please withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and owners of pets who need alternative treatment options to comment on its provisions before it is implemented.

Respectfully,

David Mayer, P.D.

Pharmacist

cc: Mark McClellan, M.D. Ph.D. FDA Commissioner at 301-443-3100

cc: IACP at 281-495-0602.

cc: Representative Chris John cc: Representative Billy Tauzin

cc: Senator John Breaux cc: Senator Mary Landrieu

cc: Representative David Vitter

cc: Representative Richard Baker

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Oct. 16 2003 03:25PM P15

FROARTSPHARMACY

FAX NO.: 3379919844



Professional Arts Phannacy

Prescription Compounding Specialist

Eric Vulrine, P.D. F.A.C.A. Mandie Romero, P.D.
Germaine Robinson, R.Ph. David Mayer; P.D.
Kevin LaGrange, R.Ph. Lynn Darby, P.D.

October 15, 2003

Subject: Veterinary Pharmaceutical Compounding

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Please withdraw the CPG and reissue it in-draft-form to allow for pharmacists, veterinarians, and owners of pets who need alternative treatment options to comment on its provisions before it is implemented:

Respectfully. Columbon, P.D.

Germaine Robinson, P.D.

Pharmacist

cc: Mark McClellan, M.D. Ph.D. FDA Commissioner at 301-443-3100

cc: IACP at 281-495-0602

cc: Representative Chris John cc: Representative Billy Tauzin

cc: Senator John Breaux cc: Senator Mary Landrièu

cc: Representative David Vitter

cc: Representative Richard Baker

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Oct. 16 2003 03:25PM P16

FROM : PROARTSPHARMACY

FAX NO. : 3379919844



Professional Arts Pharmacy

Prescription Compounding Specialist

Enc Vidrine, P.D. F.A.C. A. Mandie Romero, P.D. Germaine Robinson, R.Ph. David Mayer, P.D. Kevin LaGrange, R.Ph. Lynn Darby, P.D.

October 15, 2003

Subject: Veterinary Pharmaceutical Compounding

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Please withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and owners of pets who need alternative treatment options to comment on its provisions before it is implemented:

Respectfully,

Mandie Romero, P.D.

Pharmacist

cc: Mark McClellan, M.D. Ph.D. FDA Commissioner at 301-443-3100

cc: IACP at 281-495-0602

cc: Representative Chris John

cc: Senator John Breaux

cc: Representative Billy Tauzin

cc: Senator Mary Landrieu

cc: Representative David Vitter

cc: Representative Richard Baker

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Dct. 16 2003 03:26PM P17

FAX NO. : 3379919844



Professional Arts Phannacy

Prescoption Compounding Specialist

Eric Vidrine, P.D. F.A.C.A. Mandie Romero, P.D. Germaine Robinson, R.Ph. David Mayer; F.D. Kevin LaGrange, R.Ph. Lynn Darby, P.D.

October 15, 2003

FROM: PROARTSPHARMACY

Subject: Veterinary Pharmaceutical Compounding

atie Domak Doug

Dear Steven Sundlof, FDA Director,

The Center for Veterinary Medicine, U.S. FDA has issued a Compliance Policy Guide which threatens the pharmacists ability to formulate many medications for veterinary patients (pets).

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Please withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and owners of pets who need alternative treatment options to comment on its provisions before it is implemented:

Respectfully,

Katie Fung

Receptionist

cc: Mark McClellan; M.D. Ph.D. FDA Commissioner at 301-443-3100

cc: IACP at 281-495-0602

cc: Representative Chris John cc: Representative Billy Tauzin-

cc: Senator John Breaux cc: Senator Mary Landrieu

cc: Representative David Vitter

cc: Representative Richard Baker

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Professional Arts Pharmacy

Prescription Compounding Specialist

Mandie Romero, P.D. Enc Vulrine, PD FA.C.A. Germaine Robinson, R.Ph David Mason, P.D.

Kevin LaGrange, R.Ph Lynn Darby, P.D.

October 15, 2003

Subject: Veterinary Pharmaceutical Compounding

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Administrative Xssistan

cc: Mark McClellan, M.D. Ph.D. FDA Commissioner at 301-443-3100

cc: IACP at 281-495-0602

cc: Representative Chris John

cc: Senator John Breaux

cc: Representative Billy Tauzin

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cc: Senator Mary Landrieu

cc: Representative Richard Baker

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FROM: PROARTSPHARMACY FAX NO, : 3379919844 Oct. 16 2003 03:13PM P3



Professional Arts Pharmacy Prescription Compounding Specialist

Eric Vidrine, P.D. F.A.C.A. Mandie Romero, P.D. Germaine Robinson, R.Ph. David Mayer, P.D. Kevin LaGrange, R.Ph. Lynn Darby, P.D.

October 15, 2003

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Please withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and owners of pets who need alternative treatment options to comment on its provisions before it is implemented.

Respectfully,

Tina Stevens

Accounting Department

cc: Mark McClellan, M.D. Ph.D. FDA Commissioner at 301-443-3100

cc: IACP at 281-495-0602

cc: Representative Chris John

cc: Senator John Breaux cc: Senator Mary Landrieu

cc: Representative Billy Tauzin cc: Representative David Vitter.

.

cc: Representative Richard Baker

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Professional Arts Pharmacy

Prescription Companieding Specialist

Germaine Robinson, R.Ph David Mayer, P.D.
Kevin LaGrange, R.Ph Lynn Darby, P.D.

October 15, 2003

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Please withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and owners of pets who need alternative treatment options to comment on its provisions before it is implemented.

Respectfully,

Kerry Menard

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Professional Arts Pharmacy

Prescription Compounding Specialist

Enc Vidrine, P.D. F.A.C.A. Mandie Romero, P.D. Germaine Robinson, R.Ph. David Mayer, P.D.

Kevin LaGrange, R.Ph. Lynn Darby; P.D.



807 Third Avenue • New Brighton, Pennsylvania 15066 (724) 891-7383 • FAX (724) 891-6546

1026 Pennsylvania Ave. • Monaca, Pennsylvania 15061 (724) 775-2225 • FAX (724) 775-2282

24 HOUR EMERGENCY SERVICE (724) 891-PETE

Dr. Stephen Sundlof/ Director
Center for Veterinary Medicine
US Food and Drug Administration (HFV-1),
7500 Standish Place
Rockville, MD 20855

Dear Dr. Stephen Sundlof:

This letter is on behalf of <u>PETE'S APOTHECARY DRUGS AND COMPOUNDING STORES</u>. Regarding the recently issued Compliance Policy Guide on compounding for animals disallowing all compounding from bulk pharmaceutical ingredients that the U.S. Food and Drug Administration Center for Veterinary Medicine has issued.

The FDA's prohibition in the CPG against compounding from bulk active, pharmaceuticals is extremely problematic in that it is essential that pharmacists be allowed to compound for non-food producing animals from bulk-drug substances.

We are asking the FDA to please withdraw the CPG and reissue it in draft form. We believe this move is possibly a violation of FDA Good Guidance Practice and that many of the requirements of this CPG are extremely problematic. We believe our request is a fair one, in that it would allow pharmacists, veterinarians and patients the opportunity to comment on its provisions before it is implemented.

Thank-you for your time and consideration in this matter.

Respectfully,

Peter J. Antinopoulos RPh. CCS

Owner

Annette J. Costanza

Human Resource Directors

Flyers enclosed

cc: Mark McClellan, FDA Commissioner.

cc: Honorable Jerry LcValle, Senator

cc: Honorable Mike Veon, State Representative

cc: Honorable Melissa Hart, Congresswoman



36C Catoctin Circle, S.E. . Leesburg, VA 2017: . (703) 777-5333 FAX 703-777-5160

October 16, 2003

Dr. Stephen Sundlor Director
Contender Veterings Medicine
L.S. Food and Drug Administration (HFV-1)
To 1 Standish Place
Reckville, MD 20855

Dr. Sunalof:

It has recently come to our attention that the FDA has issued a Compliance Policy Guide CPG) on veterinary compounding. Leesburg pharmacy is an independent pharmacy that has been in business in Northern Virginia for over 25 years. We compound prescriptions for human use, as well as for non-food producing animals.

The FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound from bulk drug substances. Many of our cats and dogs have special needs that are only met through bulk compounding. We have many dogs well controlled on potassium bromide and our feline population would be in trouble without access to Cisapride.

We understand the concern of medication use in food producing animals, thus creating a need for certain guidelines. However, this CPG will negatively impact the quality of care for necessitoid pets.

The CVM issued the final form of this CPG without allowing or portunity for comments, which is in violation of the FDA Good Guidance Practices. Many requirements of this CPG are corp troublesome and deserve a comment period before being put into effect. We would appreciate the consideration of withdrawing the CPG and reissuing it in draft form to allow for intermedists, veterinarians, and patients to comment on its provisions before it is implemented.

Hank You.

Cherl Garvin, RPh

rhalimacy Manager

CC: FDA Commissioner, Mark McClellan, MD, PhD. IACP

Senator John Warner Senator George Allen

Representative Frank Wolf

KEEFER'S PHARMACY

COMPOUNDED PRESCRIPTIONS MEDICAL SUPPLIES CONSULTANT SERVICE



5 W. Prospect Ave. Mt. Prospect, IL 60056 Phone: 647-255-3220 Fax: 647-255-7568

10-9-03

Dn Stephon Sundlof, Direction Content for Veterinaly Medicins U.S. Flood and Drug Robinstrations (HFV-1) 7500 Stondish Floop Rockerlle, MD: 20855

the Center for Veterinary Medecial issued a CPG in final forms without allowing an apportunity for comments, in violations of ADA good compleones proctices. Mony of the CPG requirements are extremely problematic. and decerned a common period before being pr FDA! sprohibition in this CPG agount compounding from Bulk active phormaceuticols is extremely It is essential that phermaces be allowed to compound for NON-Food producing animals from bulk substince their outness will suffer deserse and broken hearts as pets suffer and die I ask the FDA to withdrow the CPG and ressure it in droft form to allow for pharmout veterinarios and saticuts to commen

fore et es implemental

Succeeli

CC MARK Mª CLEURN FDA.

CC HENRY HYGE CONGRESSMEN

CC MARK KIKK CONGRESS MON

CC DENUIS HAStrent, Spien Rove



PRESCRIPTION ALTERNATIVES

A Compounding & Natural Pharmaey

610 Main St.

PO Box 897

Frisco CO 80443

970-668-8482

Fax: 970-668-8492

E-mail: RxAlt@aol.com

Dr. Stephen F. Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855

17 October, 2003

Dear Dr. Sundlof:

As a pharmacist with a compounding-only pharmacy, I am very distressed with the recent Compliance Policy Guide on compounding for animals using bulk chemicals.

First of all, CVM issued this Compliance Policy Guide (CPG) in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of the CPG are extremely problematic and deserve a comment period before being put into effect.

FDA's prohibition in the CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non food-producing animals from bulk drug substances. I have so many pet owners thankful that I am here and able to provide them with necessary medications. This is especially true with cat owners, since cats are such difficult (and many times impossible) animals to pill. Hyperthyroidism is a common problem in older cats. Methimazole tablets are available, but can't be used to make the transdermal medication that the owner can rub into the hairless part of the car. This is also true for some antibiotics. Diethylstilbestrol is only available as a bulk chemical, and is excellent for incontinent female dogs.

I am asking you to withdraw the CPG and reissue it in draft form to allow pharmacists, veterinarians and patients to comment on its provisions before it is implemented.

Sincerely,

Janet Carter, Registered Pharmacist
Owner/Prescription Alternatives

Mjc555@aol.com

cc: Mark McClellan, FDA Commissioner

cc: Ben Nighthorse Campbell, Colorado State Senator

cc: Wayne Allard, Colorado State Senator

cc: Mark Udall, District Representative



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Specializing in Custom and Storile Compounding

Dr. Stephen Sundolf, Director
Center for Veterinary Medicine
U.S Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

10/20/03

Dear Dr. Sundolf:

Our pharmacy provides a valuable function working in conjunction with our vets. FDA's prohibition in this Compliance Policy Guide against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances. At Heiber's Pharmacy, we have the training and the equipment for transdermal gets as well as sterile injectables and eye drops. If we are denied compounding for pets, our pets would be the losers.

The Center for Veterinary Medicine issued this CPG in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect.

Please feel free to give me a call.

Thank you,

Joe Bettinger

Registered Pharmacist Heiber's Pharmacy

KA cc:

Mark Mclellan, FDA Commissioner

Rick Santorum, R-PA Arlen Specter, R-PA Melissa Hart, R-PA-4 Bill Shuster, R-PA-9 John Murtha, R-PA-12 Mike Doyle, R-PA-14 Timothy Murphy, R-PA-18

IACP



300 West 11th Street • Williston, North Dakota 58801 • Telephone (701) 774-3923 • 1-800-735-6954

October 20, 2003

Dr. Stephen Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855

Dear Dr. Sundlof:

My name is Dave Robinson, R.Ph., I'm a pharmacist in Williston, ND. I own and operate a pharmacy in my city, where I have a working relationship with one of our local veterinary clinics. I'm writing to you today to express my concern regarding a Compliance Policy Guide issued by the CVM in final form without allowing an opportunity for comments, which, is in violation of the FDA Good Guidance Practices. There are serious issues that will create problems for the many pets we currently supply with life saving medications. Our inability to use bulk active pharmaceuticals is extremely problematic. We compound dosage forms that will be much less effective if we must crush tablets and have tablet excipients interfering with the final product. The veterinarians we work with understand how we compound, and that the quality of the final compound will not be as good if we are no longer allowed to use bulk active pharmaceuticals.

I'm asking you to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Thank you,

David A. Robinson, R.Ph.

Rx Plus, Inc 300 W. 11th Street Williston, ND 58801

E-mail: rxplus@skylandnd.net

cc: Mark McClellan, FDA Commissioner

Senator Byron Dorgan Senator Kent Conrad

International Academy of Compounding Pharmacists.



October 16, 2003

Dr. Stephen Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855

Dr. Sundlof:

It has recently come to our attention that the FDA has issued a Compliance Policy Guide (CPG) on veterinary compounding. Leesburg pharmacy is an independent pharmacy that has been in business in Northern Virginia for over 25 years. We compound prescriptions for human use, as well as for non-food producing animals.

The FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound from bulk drug substances. Many of our cats and dogs have special needs that are only met through bulk compounding. We have many dogs well controlled on potassium bromide and our feline population would be in trouble without access to Cisapride.

We understand the concern of medication use in food producing animals, thus creating a need for certain guidelines. However, this CPG will negatively impact the quality of care for household pets.

The CVM issued the final form of this CPG without allowing opportunity for comments, which is in violation of the FDA Good Guidance Practices. Many requirements of this CPG are very troublesome and deserve a comment period before being put into effect. We would appreciate the consideration of withdrawing the CPG and reissuing it in draft form to allow for obarmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Thank You.

Jay Gill Pharm.D.

Compounding Pharmacist

CC: 1DA Commissioner, Mark McClellan, MD, PhD.

IACP

Senator John Warner Schator George Allen Representative Frank Wolf

Specializing in Custom Compounding



October 16, 2003

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Dr. Sundlof:

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Thank You,

Gretchen Brush. Pharm.D.

Mickelan Brush-

Staff Pharmacist

CC: FDA Commissioner, Mark McClellan: MD: PhD.

IACP

Senator John Warner Schator George Allen Representative Frank Wolf P.O. Box 835 717 E. Main Ave. Bismarck, ND 58501 Pharmacy: (701) 255-1881 Toll Free: 1-800-290-7028-Fax: (701) 255-7226

Dr. Stephen Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dr. Sundlof,

The CVM recently issued a Compliance Policy Guide (CPG) regarding the practice of compounding prescriptions from bulk pharmaceutical ingredients. This was done in final form without allowing opportunity for public comments.

Many requirements of this CPG are problematic and deserve a comment period before being put into effect. The FDA's prohibition-in-this-CPG against compounding from bulk active pharmaceuticals would take away our ability to treat non-food producing animals within the treatment algorithm presently in place. I have on numerous occasions received prescriptions for a companion animal that must be specially flavored or formulated into a transdermal preparation to assure the health and wellness of that patient. I have in fact experienced a few cases where a prescription compound has diverted a pet from having to be euthenized because all other treatments have failed.

Please withdraw the CPG as it is and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Sincerely

Kevin Oberlander, R.Ph.

Compounding Pharmacist/Owner

Well-Att

Dakota Pharmacy

717 E Main

Bismarck, ND 58501

(701) 255-1881, (701) 255-7226 (fax)-

otisrs@dakotarx.com

Cc: Mark McClellan, FDA Commissioner
Representative Earl Pomeroy (D-ND)
Senator Byron Dorgan (D-ND)
Senator Kent Conrad (D-ND)
International Academy Of Compounding Pharmacists

P.O. Box 835 717 E. Main Ave. Bismarck, ND 58501 Pharmacy: (701) 255-1881 Toll Pree: 1-800-290-7028 Fax: (701) 255-7226

IMPORTANT NOTICE

The Center for Veterinary Medicine (CVM) of the U.S. Food and Drug: Administration recently issued a Compliance Policy Guide (CPG) that would disallow the formulation of customized prescriptions for animals from bulk pharmaceutical ingredients. In a nutshell the CVM is saying that we can grind up a tablet and compound a grossly ineffective preparation, but it would be illegal to use the raw material to make a more stable, palatable compound. I am a member of the International Academy of Compounding Pharmacists that is implementing a letter writing campaign encouraging the FDA to withdraw this ridiculous CPG and reissue it in draft form for public review. I have enclosed a sample letter and would ask for your support. A letter should be sent to:

Dr. Stephen Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug-Administration (HFV-1) 7500 Standish Place Rockville, MD 20855-

Also fax a complete letter to:

- a) Dr Stephen Sundlof @ (301) 827-4401
- b) FDA Commissioner Mark McClellan, MD, PhD @ (301) 443-3100
- c) Representative Earl Pomeroy @ (202):226-0893
- d) Senator Byron Dorgan @ (202) 224-1193
- e) Senator Kent Conrad @ (202) 224-7776
- f) Dr. Michael Chaddock, Director of AVMA Government Relations Division @ (202) 842-4360
- g) IACP @ (281) 495-0602

HAMMUNE AR.

Be sure to include the cc: at the bottom of your letter so that Dr. Sundlof is aware of who has received letters. I appreciate your help in the effort to assure that we may continue to treat our clients with the very best we can offer.

Kevin Oberlander, RPh-

SAMPLE LETTER

Dr. Stephen Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855

Dr. Sundlof,

The CVM recently issued a Compliance Policy Guide (CPG) regarding the ability to prescribe and for our pharmacists to compound prescriptions from bulk pharmaceutical ingredients. This was done in final form without allowing opportunity for public comments.

Many requirements of this CPG are problematic and deserve a comment period before being put into effect. The FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals would take away our ability to treat non-food producing animals with in the treatment algorithm presently in place. I have on numerous occasions needed to prescribe a compound for a dog or cat that must be specially flavored or formulated into a transdermal preparation to assure the health and wellness that patient.

Please withdraw the CPG as it is and reissue it in draft form to allow for pharmacists; veterinarians, and patients to comment on its provisions before it is implemented.

Sign letter with name, title, address and contact information (i.e. phone, fax, email)

Cc: Mark McClellan, FDA Commissioner Representative Earl Pomeroy (D-ND) Senator Byron Dorgan (D-ND) Senator Kent Conrad (D-ND) Dr. Michael Chaddock, AVMA Government Relations International Academy Of Compounding Pharmacists Dr. Stephen Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855 (301) 827-4401

Dear Director Sundlof,

I am writing because of concerns about the Veterinary CGP issued by the FDA and it's adverse impact on my pharmacy and the patients I serve.

Please reconsider and withdraw this CPG and reissue it in draft form to allow for a comment period to allow pharmacists, veterinarians and the owners of my patients.

There are several bulk pharmaceuticals that I use to compound medication for cats and dogs. To restrict this use would have major impact on the lives of these animals. I believe it is essential for pharmacy to have access to bulk chemicals when working with veterinarians to provide medications compounded for animals that need them - especially our 4-legged family members.

Sincerely,

Michael W. Anneken **Custom Prescriptions** 1894 Ashwood Cr.

Ft. Wright, Ky. 41011

(859) 426-5222

(859) 426-4122 fax

rph@one.net

cc: Mark McClellan, FDA Commissioner (301) 201

mill W. ac

cc: Senator Jim Bunning cc: Representative Ken Lucas

cc: IACP



Dr. Stephen Suriclo? Director Center for Veterinary Mectains US Food and Drug Adm. histation (1.f/V-1) 1500 Standish Pigos Rockville, MD 20855

Oc. abar 3, 2003

Des Dr Smulcit

It has come to my attention that the Center for Vetterbary Medicine has issued a Configliance Policy. Goods relating to compounding prescriptions for non-flood producing animals and that the number confirment period was given. Setting up a guide without a put from those affected each have secrous, unintended consequences.

Not allowing pharmacists to compound, on a veterinarian's order, from but a pharmaceuticals is unnecessarily restrictive and interferes with each State's Board of Pharmacy regulatory practices. Should Section Charms have to pill their cat, risking bites and scrateness and traditionizing them, where we can compound a figuration of the same medication? Should owners of large dogs be told that they have to fight with the unimal to give them medication?

Octopounding in New Hampshire is we'll regulated by our State Board of Pharmony. We are inspected on a regular has sito make sure that we are in confipiiance. Having federal regulations added will only increase turbifficulty it serving our animal patients. I am especially disturbed that no one was given the opportunity to comment of the CPO. Please reissue the CPO in draft form so that the public can comment before it is implemented.

Thank . oil

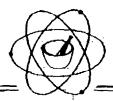
Icffrey W. Frazec, RPh Chief Pharmacist The Prescription Center Tel (602)224-9591

Fax (603)224-536.

iter zook proserintum-penter com

ec. Mark McClellar, MD, Ph.D U.S. Schafor Lidd Grego U.S. Representative Charles Bass IACP

123 North Main Street Conduct NH 03301 Tel (603) 224 9591 pt (200 870-7032 Fax (603) 229-0050



John W. Andrews

PHARMACIST (Compounding Pharmacist).

October 3, 2003

Dr. Stephen F. Sundlof, Director Center for Veterinary Medicine. U.S. Food and Drug Administration 7500 Standish Place Rockville, MD 20855

Dr. Sundlof:

CVM issued this Compliance Policy Guide (CPG) in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices.

Many requirements of the CPG are extremely problematic and deserve a comment period before being put into effect.

FDA's prohibition in the CPG against compounding from bulk active pharmaceuticals is <u>extremely problematic</u>. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances. Do you have a pet?

I am asking the FDA to withdraw the CPG and reissue it in draft form to allow for pharmacies, veterinarians and patients to comment on its provisions <u>before</u> it is implemented.

Sincerely,

John W. Andrews, RPh.

Jh v. andrew, rot

Cc: FDA Commissioner, Mark McClellan, MD,PH.D. Senator John Edwards, Senator Elizabeth Dole, Representative Richard Burr and IACP Dr. Stephen Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)7500 Standish Place
Rockville, MD 20855-

Dear Dr. Sundlof,

I am writing you to express my concerns over the Center for Veterinary Medicine issuing the Compliance Policy Guide (CPG) in final form without allowing for comments. This is in violation of FDA Good Guidance Practices. I feel that many requirements of this CPG will be extremely problematic and deserve a comment period before being put into effect.

FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk substances. I could give endless examples of how-this will affect the animals, owners and how veterinarians practice medicine. I have numerous patients that are on maintenance drug therapy that is only available compounded from bulk chemical. It will be devastating to the animal and owner if this drug therapy is no longer available. In many of the cases that I am referring to, the compounded drug is the only option for therapy!

I urge you to advise the FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Sincerely,

Jan R. Gerber, R.Ph.

3510 N. Ridge Rd., Suite 900

Wichita, Ks 67205 Phone: 316-721-2626 Fax: 316-721-4823

E-mail: igcrber@customrx.net

cc: Mark McClellan, FDA Commissioner

cc: Senator Sam Brownback: cc: Representative Todd Tiahrt

cc: IACP



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Compounding Pharmacists

Douglas Boudreaux, P.D. • Clint Daniel, P.D.

Dr. Stephen Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration 7500 Standish Place Rockville, Maryland 20855

Dear Dr. Sundloff:

I am writing you in reference to the recent Compliance Policy Guide issued on compounding for animals. As I'm sure you are aware, this Policy Guide disallows all compounding from bulk pharmaceutical ingredients, a standard which is more restrictive than the F.D.A. s policies governing compounding for humans, and one that, as a small independent compounding pharmacy, will negatively effect our ability to assist the small animal Veterinary Clinics in our area.

CVM issued this Compliance Policy Guide in final form without allowing an opportunity for comments, which is in violation of F.D.A. Good Guidance Practices. Many requirements of this Compliance Policy Guide are extremely problematic, and deserve a comment period before being put into effect. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

I am sending you this letter as a formal request for the F.D.A. to withdraw this Compliance Policy Guide and reissue it in draft form, allowing time for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented. Your consideration and assistance in this matter would be greatly appreciated.

Sincerely yours.

Clint Daniel P.D.

cc. Dr. Michael Chaddock; A.V.M.A. Government Relations Division Dr. Mark McClellan; F.D.A. Commissioner Senator John Breauux (D-La.). Senator Mary Landrieu (D-La) Representative Chris John (D-La 7th)



503 West Sallier

Lake Charles, Louisiana 70601

337-433-2290 • 800-897-7724 • Fax 337-436-7217

Companyating Pharmagists

Compounding Pharmaeists

Douglas Boudreaux, P.D. • Clint Daniel, P.D.

TO: ALL VETERINARIANS

FROM: JOHN BLEICH

SUBJECT: F.D.A. COMPLIANCE POLICY GUIDE

THE F.D.A. RECENTLY ISSUED A COMPLIANCE POLICY GUIDE THAT THREATENS BOTH YOUR AND OUR ABILITIES TO COMPOUND MANY PRODUCTS FOR VETERINARY PATIENTS. THIS MEMO IS A REQUEST FOR YOUR ASSISTANCE IN GETTING THE F.D.A. TO WITHDRAW THIS COMPLIANCE POLICY GUIDE AND REISSUE IT IN DRAFT FORM, THEREBY ALLOWING US AN OPPORTUNITY TO COMMENT ON THE RAMIFICATIONS OF SUCH AN ACTION, AS ALLOWED BY THE F.D.A.'S GOOD GUIDANCE PRACTICES.

PLEASE RALLY TO THE CALL BY WRITING A LETTER TO THE F.D.A. EXPRESSING YOUR CONCERNS. WE ARE ATTACHING A COPY OF THE LETTER WE ARE SENDING FOR YOUR REVIEW.

PLEASE FAX YOUR LETTER TO: STEPHEN SUNDLOF (301) 827-4401 FOR ADDITIONAL IMPACT, PLEASE CC. THE FOLLOWING:

Dr. Michael Chaddock; dir. of Avma's Government relations division (202) 842-4360 Dr. mark mcclellan; f.d.a. commissioner (301) 443-3100 Senator John Breaux (D-La) (504) 589-2533. Senator Mary Landrieu (D-La) (504) 589-4023 Representative Chris John (D-La 7th) (337)235-6072

IF YOU HAVE ANY QUESTIONS, PLEASE GIVE US A-CALL.

Line Avenue Pharmacy Inc.

1822 Line Avenue

Shreveport, Louisiana 71101

(318) 221-5114

Dr. Stephen Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855

October 3,2003

Dear Dr. Sundlof,

We are writing you today to express concern about CVM issuing a Compliance Policy Guide (CPG) in the final form without allowing an opportunity for comments. This is in violation of FDA Good Guidance Practices. We feel that there are some problems in the Compliance Policy that deserve comment. We understand that in the CPG for veterinary medicine, FDA is prohibiting compounding from bulk chemicals for non-food producing animals. This is extremely bad for the care of the veterinary patients. We have many veterinarians that rely on capable compounding pharmacists to help to make products that increase the care of their patients. This may be in a medication form or dosage that is not commercially available, a dosage form that is palatable to the animal, or mixing something to be used topically. We do not try to compete with products that are available to the veterinary practice.

We are asking the FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients family to comment on its provisions before it is implemented.

Thank you

Randy Caudle, Owner/ Pharmacist

Susan Caudle, Owner/ Pharmacist scaudle@custom-pharmacy.com

cc: Mark McClellan, MD., Ph.D Senator John Breaux Senator Mary Landrieau Representative Jim McCrery



Northwest Iowa Compounding

3204 First Street, Suite L • Emmetsburg, Iowa 50536, 712-852-2727 • 800-777-2545. • (Fax) 712-852-2975

October 6, 2003

Dr. Stephen Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855

Dear Dr. Sundlof,

CVM issued this Compliance Policy Guide (CPG) in final form with out allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect.

FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

In light of these issues, I feel the FDA should withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Sincerely,

Barbara antiku RPh

Barbara Anliker Registered Pharmacist

Northwest Iowa Compounding 3204 First Street, Sulte L Emmetsburg, Iowa 50536 712.852.2727

cc: Mark McClellan, FDA Commissioner; Senator Charles Grassley; Senator Tom Harkin; Representative Tom Latham; and IACP

Dr. Stephen Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855

Dear Dr. Sundlof,

As a veterinary compounding pharmacist in the state of Texas, I feel a great injustice has been done. When Center for Veterinary Medicine issued the Compliance Policy Guide in the final form without allowing opportunity for comments, this violated the FDA Good. Guidance Practices. Before being put into effect, many of the poorly prepared requirements of this CPG deserve a comment period.

The FDA's prohibition, in this CPG, against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances. I fear for many of the dogs and cats and their owners in my community that benefit from this form of compounding. These animals will suffer, because no other form of their medications exist unless I am allowed to compound from bulk drug substances.

I urge the FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented. Feel free to contact me to discuss this matter more fully.

Thank you for your consideration,

Shiff Bhad.

Steven Hoffart, Pharm.D. Magnolia Pharmacy, Owner

18602 FM 1488 Suite 800.

Magnolia, TX 77354

(281) 356-9089

(281) 356-9659 fax

magnoliapharmacy@ev1.net

cc: Mark McClellan, FDA Commissioner; cc: Senator John Cornyn; cc: Senator Kay

Baily Hutchison; cc: Rep. Kevin Brady



Where you need us, when you need us

October 6, 2003

Or. Stephen Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855

Dear Dr. Sundlof,

Recently the FDA has taken a position on veterinary compounding which would potentially inhibit the legitimate practice of pharmacy. This position will directly disadvantage companion pet owners throughout the United States. I wish to reiterate the following points.

(a) CVM issued this Compliance Policy Guide (CPG) in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect.

(b) FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.







Our pharmacy, through compounding, assists many pet owners with specialized needs such as seizure preparations for their dogs. Have you every watched a child's faces when their pet is having a seizure?

We strongly request the immediate withdraw of CPG and reissue a draft form for evaluation with informed and appropriate comment before implementation.

Sincerely,

Karl Clearwaters, R.Ph.

cc: Mark McClellan, FDA Commissioner

Senator Richard Lugar Senator Evan Bayh

Representative Dan Burton Representative Chris Chocola

International Academy of Compounding Pharmacist



October 6, 2003

Dr. Stephen Sundolf, D.V.M., Ph.D. Director Center for Veterinary Medicine U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855

Dear Dr. Sundolf,

This letter is in response to the recent Center for Veterlnary Medicine (CVM) Comptiance Policy Guide. (CPG) which placed restrictions on the compounding, with bulk substances, of medications for non-food producing animals. I am opposed to the CPG as is stands as it is my opinion that there are several problems with this new CPG.

First, the CVM's issuance of the CPG in its final form violates the Food and Drug Administration's own. Good Guidance Practices, as it did not allow any opportunity for comments. Many of the requirements of this CPG are extremely problematic and deserve a comment period so that all parties have an opportunity to state their comments to the FDA's CVM.

Second, I must stress that the restrictions against compounding from bulk active ingredients are extremely problematic. It is essential that pharmacists be allowed to compound from bulk drug substances for non-food producing animals.

As an example, many of our hyperthyroid feline patients use topical methimazole. The topical dosage form we compound is often the only dosage form owners are able to give their pet and keep in compliance with the dosing regimen. Due to the binders and fillers in the FDA approved tablet form of the drug we would be unable to compound a gel in a volume that would be feasible to use. Other drugs available only in capsule or tablet form can also present problems when compounding into a different dosage forms. The binders and fillers often precipitate out when making a topical gel or oral suspension. There are volumes of benefits for using bulk drugs; too many to mention in this letter.

Please withdraw the current CPG and reissue it in draft form to allow pharmacists, veterinarians, and patients to comment on its provisions before it is implemented. Should you have any questions or comments please feel free to contact me.

Douglas R. Yoch, Pharm.D. Stanley Apothecary, Inc. 3330 Monroe Road Charlotte, NC 28205 704-370-6612 704-375-5888 fax dryoch@hotmail.com

Respectfully,

Douglas R. Yoch, Pharm.D. Stanley Apothecary, Inc.

cc: Dr. Mark McClellan, M.D., Ph.D., FDA Commissioner

Senator Elizabeth Dole Senator John Edwards Representative Robin Hayes Representative Sue Myrick Representative Melvin Watt

International Academy of Compounding Pharmacists

3330 Monroe Road • Charlotte, NC 28205 • 704/370-6612 • Fax 704/375-5888

October 6, 2003

Tor. Stephen F. Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration(HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Stephen F. Sundlof,

I am writing to convey my concerns with the Compliance Policy Guide(CPG) issued that threatens my pharmacists ability to compound many products for veterinary patients. CVM issued this CPG in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect.

FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

I want to ask FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented.

Sincerely.

Ruby Willis, Pharmacy Technician

Heritage Pharmacy 1507 Springhill Avenue Mobile, AL 36604

(251)432-0718

cc: Mark McClellan, FDA Commisioner

cc: Representative Jo Bonner cc: Senator Jeff Sessions cc: Senator Richard Shelby

cc: International Academy of Compounding Pharmacists

OCT. 8, 2003

DR. STEPHEN SUNDLOF, DIRECTOR-

CENTER FOR VETERINARY MEDICINE

U.S. FOOD AND DRUG

DEAR SIR:

I AM A COMPOUNDING VETERINARY PHARMACIST IN THE EQUINE BUSINESS ONLY WE DO-NOT COMPOUND FOR FOOD GRADE ANIMALS. YOUR AGENCY HAS SEVERAL ISSUES AT HAND THAT ARE VERY DETRIMENTAL TO MY PRACTICE. THEY ARE AS FOLLOW:

- 1- CVM ISSUED THE COMPLIANCE POLICY GUIDE (CPG) IN FINAL FORM WITHOUT ALLOWING OPPORTUNITY FOR COMMENTS, IN VIOLATION OF FDA GOOD GUIDANCE PRACTICES. MANY REQUIREMENTS OF THIS CPG ARE EXTREMELY PROBLEMATIC AND DESERVE A COMMENT PERIOD BEFORE BEING-PUT INTO EFFECT.
- 2- FDA'S PROHIBITION IN THIS CPG AGAINST COMPOUNDING FROM BULK ACTIVE PHARMACEUTICALS IS EXTREMELY PROBLEMATIC. IT IS ESSENTIAL THAT PHARMACIST BE ALLOWED TO COMPOUND FOR NON-FOOD PRODUCING ANIMALS FROM BULK DRUG-SUBSTANCES.

I WOULD LIKE TO ASK THE FDA TO WITHDRAW THE CPG AND REISSUE IT IN DRAFT FORM TO ALLOW PHARMACIST, VETERINARIANS, AND PATIENTS TO COMMENT ON ITS PROVISIONS BEFORE IT IS IMPLEMENTED

SINCERILY,

JOHN W. DEMARS, RPH PO BOX 404 ST MATTHEWS, S.C. 29135 803-655-5770 FAX 803-655-5771

Cc: MARK MCCLELLEN FDA COMMISSIONER

SEN, ERNEST F HOLLINGS SEN, LINDSAY GRAHAM REP, JOE WILSON REP, JAMES CLYBURN-IACP



We care about your health."

1960 South 16th Street, Suite Two • Wilmington, NC 28401 (910) 763-1896 • FAX (910) 763-1709

October 7, 2003

Dr. Stephen Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855

Dear Dr. Sundlof:

It has come to my attention that the Center for Veterlnary Medicine recently released a final Compliance Policy Guide on customized pharmaceutical drug compounding for animals that disallows all compounding from bulk pharmaceutical ingredients. The CVM issued this Compliance Policy Guide in final form without allowing the opportunity for comments, in violation of the FDA Good Guldance Practices. Many of the CPG requirements are problematic for those of us that are trying to provide necessary pharmaceutical care for the best interest of our animal patients. We deserve a comment period before it is put into effect.

It is very important for veterinarians and compounding pharmacists to be allowed to compound customized medications from bulk active pharmaceuticals for <u>non-food producing animals</u> when, in our best professional opinion, these products will provide the best therapy for the animal. We daily provide customized medications (various dosage forms, customized dosage strengths, customized flavors, etc.) for many medical conditions (thyrold, cancer, seizures, antibiotics, cardiac, gastrointestinal, etc) and this policy will be <u>extremely problematic</u>.

I would like to ask you to withdraw the CPG and reissue it in draft form to allow pharmacists, veterinarians, and patients to comment on its provisions before it is implemented. I may be reached at my e-mail of henryherring@medicalcenterpharmacyrx.com.

Sincerely,

Henry H. Herring, R.Ph.

CC: Mark McClellan, MD, Ph.D., FDA Commissioner
Senator John Edwards (North Carolina)
Senator Elizabeth Dole (North Carolina)
Representative Michael McIntyre (North Carolina)

Vinternational Academy of Compounding Pharmacists

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Dr. Stephen F. Sundlof, Director Center for Veterinary Medicine U.S. Food and Drug Administration (HFV-1) 7500 Standish Place Rockville, MD 20855

Dear Dr. Sundlof:

As a compounding pharmacy many of our prescriptions are for pets. The policy guide not allowing use of bulk chemicals in the preparation of these prescriptions will impose many problems for the pet owners. On behalf of many of our patients please withdraw this policy guide that prohibits the use of bulk chemicals in prescription compounding. It is very difficult to explain why we can legally compound for a customers child but not their pet?

Thank you,

Pat Downing, RPh, IACP

Med-Shop Total Care

470 E. Loop 281 Longview, TX 75605

903-234-0080

903-234-1062

CC:

Mark McClellan, MD, Ph D. FDA Commissioner







Kay Balley Hutchison 10440 N. Central Expressway, #1160 Dallas, TX 75231 Phone: (214) 361-3500 Fax: (214) 361-3502

John Cornyn 221 W. 6th St., Ste 1240 Austin, TX 78701 Phone: (512) 469-6034 Fax: (512) 469-6020

Max Sandlin 1300 E. Pinecrest Dr., Ste. 700 . Marshall, TX 75870 Phone: (903) 938-8388 Fax: (903) 935-5772

Ralph Hall 104 N. San Jacinto Rockwall, TX 75087 Phone: (972) 771-91.18 Fax: (972) 772-0907

International Academy of Compounding Pharmacists (IACP) PO Box 1385
Sugarland, TX 77487
Phone: (800).927-4227
Fax: (281) 495-0602

Texas Pharmacy Association PO Box 14709 Austin, TX 78761-4709 Phone: (800) 505-5463 Fax: (512) 836-0308 October 8, 2003

IACP:

Re: copy of letter sent to FDA, CVM, President Bush, CO state senators and representative

The CVM has issued the Compliance Policy Guide (CPG) in its final form without allowing opportunity for comments from pharmacists, veterinarians and patients. This is in violation of the FDA Good Guidance Practices. Many of the requirements of this CPG are extremely problematic and deserve a comment period before being put into effect.

The FDA has prohibited pharmacists from compounding veterinary prescriptions from bulk active pharmaceuticals, the same pharmaceuticals that are acceptable for human use-It is essential that pharmacists be allowed to compound for non-food producing animals from bulk chemicals. Pharmacists use only USP and NF quality products and go to the utmost extreme to ensure the quality of the products they compound. The communities rely on independent pharmacies to carry out this function. The insurance companies, manufacturers, and chains have done well to put the independent out of business with poor reimbursement contracts, outrageous drug costs, and deep discounting below cost of goods. The independent pharmacy relies on the income from veterinary compounding to remain in business. Not only is the independent fulfilling a need in the community (which neither chains nor manufacturers want to fill, due to time-consuming efforts and short stability of the compounded products), but each is giving quality care to every individual patient. The pharmacist collaborates with the veterinarian to ensure the correct drug product is dispensed at the correct dose. He is ensuring true pharmaceutical care as it should be practiced. The independent is the person with a pager who returns calls at all hours of the night for parents of sick children, the elderly or home-bound patient. He is the one to deliver medications at patients homes in time of need. The pharmacist is the first contact between the community and physicians. Patients have relied heavily on the pharmacist's knowledge and expertise to guide them and seek appropriate care. Compounding is the right of all pharmacists. This CPG is denying pharmacists their right to compound prescriptions and veterinarians their right to prescribe for their patients accordingly.

Please ask the FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians and patients to comment on its provisions before it is implemented.

Thank you.

Sincerely,

Robin A. Hyman, Pharm.D.

RLG Hyman, Pharm. J.

Cc: Stephen Sundlof-CVM; Mark McClellan, FDA Commissioner; President Bush; Senator Campbell CO: Senator Alland CO: Representative Recurrence CO.

Senator Campbell-CO; Senator Allard-CO; Representative Beauprez-CO.